

A P P E A R A N C E S

FOR THE PLAINTIFFS:

SCOTT A. LOVE, ESQUIRE

CLARK, LOVE & HUTSON
440 Louisiana, Suite 1600
Houston, TX 77002

PAUL THOMAS FARRELL, JR., ESQUIRE

GREENE, KETCHUM, BAILEY, WALKER, FARRELL & TWEEL
419 11th Street
Huntington, WV 25701

AIMEE H. WAGSTAFF, ESQUIRE

ANDRUS WAGSTAFF PC
1999 Broadway, Suite 4150
Denver, CO 80202

DOUGLAS C. MONSOUR, ESQUIRE

THE MONSOUR LAW FIRM
404 N. Green Street
Longview, TX 75601

FOR THE DEFENDANTS:

MICHAEL BONASSO, ESQUIRE

FLAHERTY, SENSABAUGH & BONASSO, PLLC
P.O. Box 3843
Charleston, WV 25338-3843

ROBERT T. ADAMS, ESQUIRE

JON A. STRONGMAN, ESQUIRE

EVA M. WEILER, ESQUIRE

SHOOK, HARDY & BACON
2555 Grand Boulevard
Kansas City, MO 64108

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I N D E X

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(By Video)				

—Colloquy—

1 PROCEEDINGS had before The Honorable Irene C. Berger,
2 Judge, United States District Court, Southern District of West
3 Virginia, in Charleston, West Virginia, on November 04, 2014,
4 at 8:50 a.m., as follows:

5 THE COURT: Good morning, everyone.

6 It's my understanding you have a preliminary matter.

7 MR. ADAMS: We do, Your Honor, and I can be brief
8 about it.

9 Mr. Monsour was kind enough to give me his slides
10 that he's going to use with this next witness. And a couple
11 of the slides deal with opinions relating to the Directions
12 for Use which, you know, has been described as kind of a
13 manual for the Obtryx.

14 And, so, there's two slides. One is actually going
15 through the manual or the DFU, and the second slide is called
16 "Complications Not in the DFU." So, I anticipate this would
17 be a description of why the Directions for Use is not
18 appropriate because it doesn't have certain complications
19 noted in it.

20 But I object to that and I informed Mr. Monsour of
21 that. There's no discussion at all contained within this
22 expert's Rule 26 report about any criticisms of the DFU and we
23 weren't alerted to that. We didn't -- that wasn't an issue
24 that was discussed with him. So, I think it's outside the
25 scope.

Colloquy

1 I wanted to alert the Court and counsel to that
2 because I didn't want to disrupt the exam later. I thought it
3 would be best if we do it now.

4 THE COURT: Mr. Monsour.

5 MR. MONSOUR: Yes, Your Honor. I did not try to hide
6 the ball at all from Mr. Adams. I came in this morning and,
7 as he requested, I think we sent him the Power slides even
8 before they asked, not just five minutes before he came,
9 trying to give full disclosure.

10 I went through and I tracked Judge Goodwin's order.
11 And when Judge Goodwin wrote his order with regard to Dr.
12 Rosenzweig, he specifically said, "I'm going to let Dr.
13 Rosenzweig talk about general causation." And in the context
14 of general causation he even went further to say he can talk
15 about shrinkage, degradation, and those types of things.

16 Well, the, the, the portions of the DFU -- we're not
17 talking about the entirety of the DFU. But several portions
18 of the DFU that we are going to talk about relate to the
19 conditions of shrinkage and degradation.

20 And, so, it talks about the chronic problems, the
21 inability to remove the mesh. Those all have to do with the,
22 the in-growth, the shrinkage and degradation which make it
23 almost impossible.

24 So, it's going to be a situation where we're talking
25 about how the DFU relates to shrinkage and degradation which

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1 has already been allowed. And there were no limitations put
2 on Judge Goodwin's order about how far he can go on shrinkage
3 and degradation. So, I think this falls right in line with
4 Judge Goodwin's ruling, Your Honor.

5 MR. ADAMS: And, Your Honor, obviously Judge Goodwin,
6 like us, was basing his *Daubert* opinion, which is on Page 84
7 and 85, basing it upon the confines of Rule 26 which says that
8 your opinions have to be disclosed in the report.

9 There is nothing in the report concerning the DFU.
10 So, Judge Goodwin nor us addressed opinions regarding the DFU,
11 and that's why this expert shouldn't be allowed to testify
12 about it.

13 Now, I mean, that's a pretty simple argument. Mr.
14 Monsour, you know, has not pointed out anywhere in the report
15 and there's nothing in the report that contains that language
16 or those opinions.

17 THE COURT: All right. Anything further, counsel?

18 MR. MONSOUR: The only thing I would say is, Your
19 Honor, it's hard to talk about medical problems and talk about
20 every potential contingency that you might talk about.
21 Instead, we give general topics that we might talk about,
22 shrinkage and contraction.

23 Mr. Adams is a good lawyer. He knows that if we're
24 talking about shrinkage contraction that the issue of the DFU
25 might come up because it does come up because they don't warn

Colloquy

1 about it in the Directions for Use. They don't talk about how
2 because the products contract that they are difficult to
3 remove.

4 And, so, it falls under -- when you give somebody
5 like Mr. Adams notice of something like that, he knows what
6 we're going to talk about. It's not, it's not an undue
7 prejudice or anything like that. It's, it's well within what
8 we have talked about in this litigation the entire time. We
9 talk about the Directions for Use.

10 At some point in time, I don't think we should even
11 have to say that we're going to talk about the Directions for
12 Use because we talk about it everything, in everything we do.
13 It's almost an assumption.

14 THE COURT: All right, counsel, I would like to be
15 able to give you a ruling here this morning before we get
16 started so that you do not have to interrupt. But I myself
17 want to hear the context of the testimony so that I can better
18 understand and give you a more informed ruling on it.

19 I will listen carefully and make every effort to do
20 that. But listening to your arguments isn't helping me. I
21 would like to see the context.

22 Certainly, generally if it's an opinion that hasn't
23 been disclosed, that's the reason for the rule, generally
24 those are excluded. But if there is an opinion that may
25 necessarily take into consideration discussions of other

—Colloquy—

1 matters that the Judge has not excluded, it would not
2 necessarily be excluded because some sub category of opinion
3 hasn't been disclosed.

4 So, I need to hear it, see the context in which it's
5 going to be offered, and then I'll give you gentlemen a
6 ruling.

7 MR. MONSOUR: Thank you.

8 MR. ADAMS: Your Honor, would it be helpful for you
9 to have his expert report?

10 THE COURT: I do have it. I'm sorry. Yes, give me
11 the expert report.

12 MS. WEILER: Your Honor --

13 THE COURT: Yes, ma'am.

14 MS. WEILER: -- we're also wondering if we could move
15 a joint exhibit, the medical records in at this time.

16 THE COURT: All right.

17 MS. WEILER: As joint, joint exhibit we'd like to
18 move the medical records of Ms. Tyree, and then separately as
19 a joint exhibit the medical records of Ms. Blankenship. We
20 would also like to do that for Ms. Wilson a little bit later,
21 but we wanted to make sure we have the redactions right on
22 that one.

23 THE COURT: All right. You want to give me, Ms.
24 Weiler, the number of the exhibits and then I'll inquire if
25 there's anything additional that the plaintiffs want to add

—Colloquy—

1 with respect to that motion.

2 MR. MONSOUR: Your Honor, would you like a copy of
3 the *Daubert* opinion with regard to Dr. Rosenzweig?

4 THE COURT: I have that.

5 MR. MONSOUR: Okay, all right.

6 THE COURT: I'm sorry, Ms. Weiler. Mr. Monsour was
7 being very discourteous to you. Go ahead.

8 MS. WEILER: Thank you, Your Honor.

9 Do you want all the exhibit numbers for each one of
10 the exhibits within that joint collection?

11 THE COURT: So, it's not a collective exhibit then?

12 MS. WEILER: We've done one exhibit number per, per
13 provider per plaintiff. So, I'm happy to read all of those,
14 whatever is most convenient for the Court.

15 THE COURT: I want the record to be clear as to
16 what's being offered, so let's go through it, please.

17 MS. WEILER: Okay. So, we'd like to offer Joint
18 Exhibit Number 61, the medical records of Ryan FitzWater for
19 Ms. Tyree; Joint Exhibit Number 62, the medical records of Ms.
20 Tyree from Dr. John Hannah; Exhibit Number 63, medical records
21 of Ms. Tyree from Dr. Joshua Lohri; Exhibit Number 64, Ms.
22 Tyree's medical records from Dr. Bernard Luby; Exhibit Number
23 65, medical records of Ms. Tyree from Dr. David Patton;
24 Exhibit Number 66, medical records of Ms. Tyree from Dr.
25 Matthew Upton; Exhibit -- hold on one second. Sorry.

—Colloquy—

1 Actually, Number 66 is the medical record of Ms. Tyree as to
2 Thomas Memorial Hospital; Exhibit Number 67 is the medical
3 record of Ms. Tyree as to Dr. Matthew Upton; Exhibit Number 68
4 are the pharmacy records of Ms. Tyree from CVS Pharmacy.
5 That's all for plaintiff Tyree, Your Honor.

6 THE COURT: With respect to plaintiff Tyree is there
7 anything further that the plaintiffs want to put on the record
8 with respect to the motion to admit those joint exhibits into
9 evidence?

10 MS. WAGSTAFF: Yes, Your Honor. This is Aimee
11 Wagstaff. We were handed this morning some medical bills
12 relating to Ms. Tyree. I don't know if you're intending to
13 use these with her or not, but we would object to admitting
14 any medical bills with relation to her treatment. We're not
15 seeking medical expenses or the recovery of them.

16 MR. BONASSO: They're in the, they're in the -- may I
17 respond, Your Honor?

18 THE COURT: Sure.

19 MR. BONASSO: Ms. Weiler was speaking. Those bills
20 were in the records. They're a part of the record. I believe
21 it goes to the treatment that she had and the amount of
22 treatment she had. They total about \$16,000 for the two
23 surgeries that she had. And I don't really intend to post the
24 records in front of the jury, but I do intend to ask Ms.
25 Blankenship if she recalls that and may demonstrate a summary

—Colloquy—

1 slide. It's relevant to the extent of plaintiff's claimed
2 damages.

3 THE COURT: It's my understanding that they are not
4 claiming those medical damages. Is that correct?

5 MS. WAGSTAFF: That's correct, Your Honor.

6 THE COURT: Then in an effort to ensure that there is
7 no confusion on the jury's part and looking at these exhibits
8 that are admitted, I'm going to exclude that portion from the
9 records.

10 And I preserve, Mr. Bonasso, an objection and
11 exception for the defendants.

12 Anything else with respect to the motion of joint
13 exhibits related to plaintiff Tyree?

14 MR. LOVE: We have nothing further, Your Honor.

15 THE COURT: Ms. Weiler, those exhibits will be
16 admitted into evidence.

17 MS. WEILER: Thank you, Your Honor. May I do the
18 same for Ms. Blankenship as well?

19 THE COURT: Yes, ma'am.

20 MS. WEILER: I'd like to move for Joint Exhibit
21 Number 1, which are the Access Health records pertinent to Ms.
22 Blankenship; Exhibit Number 2, the CAMC Health Systems, Inc.,
23 records pertinent to Ms. Blankenship; Exhibit Number 3, the
24 CAMC lab records pertinent to Ms. Blankenship; Exhibit Number
25 4, the Camden on Gauley Medical Center records pertinent as to

—Colloquy—

1 Ms. Blankenship; Exhibit Number 5, the medical records of Ms.
2 Blankenship from Dr. Susan Capelle; Exhibit Number 6, the CVS
3 Pharmacy records pertinent to Ms. Blankenship; Exhibit Number
4 7, the medical records from Carlotta Ray Evans, M.D.,
5 pertinent to Ms. Blankenship; Exhibit Number 8, Ms.
6 Blankenship's records from Greenbrier Valley Medical Center;
7 Exhibit Number 9, medical records regarding Ms. Blankenship
8 from Monongalia General Hospital; Exhibit Number 10, the
9 records regarding -- I'll drop that one -- Exhibit Number 11,
10 medical records of Ms. Blankenship from Dr. Marnie Moose,
11 actually FMP Marnie Moose; the pharmacy records regarding Ms.
12 Blankenship from Mountain Lake Pharmacy; --

13 MS. WAGSTAFF: Your Honor, maybe to speed this up we
14 could just say that we have no objection to any of those
15 records coming in with the exception of the medical bills that
16 we discussed.

17 THE COURT: She has moved on to a different
18 plaintiff. I've ruled on the admissibility of those related
19 to Ms. Tyree which is the plaintiff that I thought the issue
20 was with respect to the medical bills.

21 MS. WAGSTAFF: Your Honor, Ms. Blankenship is not
22 making a claim for medical bills either and --

23 MS. WEILER: Your Honor, I'm not asking -- I'm not
24 asking to have admitted the medical bills. I'm just going
25 through medical records for exhibit purposes.

—Colloquy—

1 THE COURT: All right. Go ahead, please.

2 MS. WEILER: Pharmacy records of Ms. Blankenship as
3 Exhibit 13; the medical records of Ms. Blankenship from
4 Dr. Jodie Posey as Exhibit 14; medical records of Ms.
5 Blankenship from Dr. David Rainey as Exhibit 16; medical
6 records of Ms. Blankenship from Robert Stanley D.O. as Exhibit
7 17; medical records regarding Ms. Blankenship for Summersville
8 Regional Medical Center as Exhibit 18; and Exhibit 19 are the
9 medical records regarding Ms. Blankenship from Summersville
10 Rural Health Clinic; and, finally, medical records regarding
11 Ms. Blankenship from Dr. Robert Wheeler as Exhibit 20, Your
12 Honor.

13 THE COURT: All right. There was no 12. Is that
14 correct?

15 MS. WEILER: That's correct. I pulled out the
16 billing records, Your Honor.

17 THE COURT: All right. Your -- is there anything
18 from the plaintiffs with respect to the motion to move those
19 joint exhibits relative to this defendant?

20 MS. WAGSTAFF: Nothing, Your Honor, no objection.

21 THE COURT: All right. Ms. Weiler, your motion will
22 be granted and those exhibits will be admitted into evidence.

23 (Plaintiffs' Exhibits 61, 62, 63, 64, 65, 66, 67, 68,
24 1, 2, 3, 4, 5, 6, 7, 8, 9, 11, 13, 14, 16, 17, 18, 19, and 20
25 were received in evidence.)

Colloquy

1 MS. WEILER: Thank you, Your Honor.

2 MR. LOVE: One other housekeeping matter, Your Honor.

3 THE COURT: Yes, sir.

4 MR. LOVE: I don't want to keep the jury waiting and
5 I can do this at the Court's convenience, but we had three
6 video deposition cuts played with exhibits yesterday. And at
7 some point in time at your convenience I'd like to offer those
8 into evidence.

9 THE COURT: All right. Let's get the jury and if you
10 will remind me at a break, I'll take care of that, Mr. Love.

11 MR. LOVE: Thank you.

12 (Jury returned into the courtroom at 9:05 a.m.)

13 THE COURT: Good morning, ladies and gentlemen. You
14 can be seated.

15 Call your next witness, please.

16 MR. MONSOUR: Your Honor, at this point in time, we
17 would call Dr. Bruce Rosenzweig, our expert urogynecologist.

18 THE COURT: Sir, would you come up and take an oath
19 or affirmation, please.

20 (BRUCE ROSENZWEIG, HAVING BEEN DULY SWORN, TESTIFIED
21 AS FOLLOWS:)

22 MR. MONSOUR: Your Honor, at this point in time I've
23 been instructed that I need to ask you to turn on the monitor.

24 THE COURT: All right.

25 MR. MONSOUR: Thank you. Your Honor, for some reason

—Rosenzweig - Direct - Monsour—

1 it doesn't seem to be working back there. We've got it right
2 here. Okay. Now it's working. Thank you.

3 (DIRECT EXAMINATION OF BRUCE ROSENZWEIG BY MR. MONSOUR:)

4 Q. Good morning.

5 A. Good morning, sir.

6 Q. Would you please introduce yourself to the ladies and
7 gentlemen of the jury.

8 A. Good morning. My name is Dr. Bruce Rosenzweig.

9 Q. And what kind of a doctor are you?

10 A. I'm a gynecologist and a urogynecologist.

11 Q. Okay. We're going to talk about several subject areas
12 today. What I'd first like to do is get a little bit of your
13 background, and then I want to kind of give the jury an idea
14 of some of the things that we talk about. So, first I want to
15 talk about who you are and then I want to give the jury a
16 little bit of a road map of some of the subjects that we're
17 going to be talking about. Okay?

18 A. Okay.

19 Q. So, let's talk about your background and training. Where
20 did you get your medical degree from?

21 A. I went to the University of Michigan for medical school.

22 Q. Okay. And then you completed residencies and pelvic
23 surgery fellowships?

24 A. That is correct. I did a four-year residency program
25 which is a post-graduate training in a specific field of

—Rosenzweig - Direct - Monsour—

1 medicine. And mine was in obstetrics and gynecology.

2 Q. Okay. And it looks like you did a urogynecology and
3 urodynamics fellowship at UCLA Medical School; correct?

4 A. That is correct.

5 Q. Is it a fair statement to say that with regard to
6 urogynecology that UCLA is one of the top institutions in the
7 world?

8 A. That is correct.

9 Q. Okay. And it also mentions here that you have been a
10 faculty member at the University of Illinois in Chicago.

11 A. That is correct.

12 Q. Okay.

13 A. I --

14 Q. Keep going.

15 A. I was an Associate Professor at the University of
16 Illinois. I also ran the residency program. That is the
17 training program that trains young doctors in the field of
18 obstetrics and gynecology.

19 Q. Okay. Now, are you board certified?

20 A. Yes, sir, I am.

21 Q. Okay. And with regard to teaching, what areas do you
22 teach in the field of medicine?

23 A. Well, I teach medical students, residents, and geriatric
24 Fellows both obstetrics -- or gynecology and also
25 urogynecology.

—Rosenzweig - Direct - Monsour—

1 Q. Okay. Have you published articles -- this case involves
2 stress urinary incontinence and pelvic floor issues. Have you
3 published in that area?

4 A. Yes, I have.

5 Q. Have you lectured in that area?

6 A. Yes, I have.

7 Q. The publications that you've published, are those
8 publications that are intended for the general public or for
9 surgeons that actually operate in that area?

10 A. The vast majority of the papers that I've written and
11 also the lectures and presentations that I've given have been
12 directed at the medical community.

13 Q. Okay. The lectures that you've given fall under the same
14 scope?

15 A. That is correct.

16 Q. Okay. Now, if you would give me an idea of -- I know
17 you're here testifying for us today. Can you give me an idea
18 of what your practice right now currently encompasses?

19 A. I currently see patients approximately two days a week.
20 I do surgery a day and a half a week. And then the rest of my
21 time is doing administrative work and other activities.

22 Q. Okay. Again, we're talking about stress urinary
23 incontinence. We're talking about polypropylene slings.
24 We're going to talk about polypropylene sling removal. Is
25 this an area that you work in pretty much on a regular basis

—Rosenzweig - Direct - Monsour—

1 every week every day?

2 A. That is correct.

3 Q. Okay. We hired you as an expert because of that; right?

4 A. That is correct.

5 Q. Okay. And to be an expert for us, did you review
6 material?

7 A. Yes, that is correct.

8 Q. And give us an idea of some of the material that you
9 reviewed.

10 A. Well, specifically I reviewed the medical records of Ms.
11 Blankenship, also deposition testimony of her deposition,
12 treating doctors' depositions. I also reviewed the medical
13 literature.

14 Q. Okay. And give us an idea of how much medical literature
15 you have reviewed at our request.

16 A. Well, I've, I continue to review the medical literature
17 just to keep up with medical literature to keep my board
18 certification active.

19 Specifically, I reviewed studies that relate to the
20 product that we're going to be talking about today, also
21 studies on complications associated with these products, and
22 other studies that we're probably going to be talking about.

23 Q. And I asked a really poor question and I apologize for
24 it. I said what studies did you read at our request. A lot
25 of the studies you read, you read whether or not you're

—Rosenzweig - Direct - Monsour—

1 working in litigation I would assume.

2 A. That is correct.

3 Q. Okay, all right. You don't come here for free. We pay
4 you for your time. Correct?

5 A. That is correct.

6 Q. And what do you charge to come testify in cases like
7 this?

8 A. I charge \$10,000 a day for trial testimony.

9 Q. Okay. That seems like a lot of money. Tell me why you
10 charge that much.

11 A. I have a busy practice. I have employees. I'm in
12 private practice so that all the expenses of my practice I
13 have to take care of. I have to offer my employees health
14 insurance, a retirement package. And also when I'm not in my
15 practice, I have to have someone that's actually there to
16 cover my practice just in case one of my patients gets sick.

17 Q. So, instead of testifying this morning, you could in
18 theory be in Chicago operating on revising a sling. True?

19 A. That is correct.

20 Q. Okay. So, let's talk about some of the areas that we're
21 going to discuss today. I want to talk to you about stress
22 urinary incontinence and its treatments. Okay?

23 I want to talk to you about the Obtryx procedure
24 itself. And that's this product right here. Okay? And we're
25 going walk the jury through a video of the Obtryx being

—Rosenzweig - Direct - Monsour—

1 implanted. It's a five-minute video.

2 I want to talk to you about polypropylene and
3 polypropylene slings. Okay?

4 Then we're going to follow up with some thoughts on the
5 Obtryx literature. Then we're going to talk about the safety
6 of Obtryx.

7 And last but not least we're going to talk about Ms.
8 Blankenship. Okay?

9 A. That's fair.

10 Q. Does that sound like a fair road map to you for today?

11 A. Yes, sir.

12 Q. Okay. So, let me ask you this. Will you agree that the
13 opinions that you give to my questions today will be based
14 upon both a reasonable medical probability and a reasonable
15 medical certainty --

16 A. Yes.

17 Q. -- unless you state otherwise?

18 A. Yes.

19 Q. Okay. Let's talk -- the opinions that you form today --
20 let's give the jury a background. The opinions that you form
21 today, what are those derived from?

22 A. They're derived from my clinical experience and review of
23 the literature.

24 Q. Okay. So, let's talk -- tell the ladies and gentlemen of
25 the jury -- you are -- in this case you are the first medical

—Rosenzweig - Direct - Monsour—

1 doctor that has testified thus far. And, so, let's give them
2 a background of the injury or the problem, the underlying
3 problem that this case is about. Since you're the first
4 doctor on the stand, I think it would be appropriate for you
5 to explain to them. Please tell us what is stress urinary
6 incontinence?

7 A. Well, stress urinary incontinence is a medical condition.
8 And with this condition a woman will actually lose her urine
9 when she coughs, sneezes, or does activities that increases
10 the pressure in the abdomen and in the pelvis.

11 Q. Okay. Is stress urinary incontinence a life-threatening
12 condition?

13 A. No, it is not.

14 Q. Okay. Is it a condition that should be downplayed?

15 A. No, obviously not. I mean, this is a problem that can be
16 a social problem or a hygienic problem. It can alter the way
17 a woman does her activities. It can alter the way she
18 interacts with her family or interacts with her spouse or
19 loved one.

20 So, it is definitely a, a condition that can have a
21 quality of life impact. But it is not a life-threatening
22 impact on the quality of life.

23 Q. Okay. What percent of stress urinary incontinence is
24 actually severe?

25 A. Well, that can be debated, but a good number to hang your

—Rosenzweig - Direct - Monsour—

1 hat on is around ten percent.

2 Q. Okay. And what would be stress -- what would be, what
3 would be severe stress urinary incontinence?

4 A. Well, there are a number of things that increase the
5 severity. One is how many times a day you actually leak.
6 Now, obviously, we don't always increase our intra-abdominal
7 pressure and there might be days when you cough more or you
8 sneeze more, but we look at the average number of days that a
9 woman leaks and the average number of times that she leaks.
10 And usually greater than one time a day leaking would make it
11 severe or if there's a significant volume that is leaked.

12 Q. Okay. There are several different types of treatment for
13 stress urinary incontinence. True?

14 A. That is correct.

15 Q. Would you please tell us all what are those?

16 A. Well, there's basically two ways to treat things. One is
17 behaviorally and one is medically. And the last one is
18 surgically.

19 Now, behaviorally what we talk about is to avoid things
20 that could cause you to increase your intra-abdominal
21 pressure. So, if you have a chronic cough, have the chronic
22 cough treated. If you have seasonal allergies, treat the
23 seasonal allergies so that you decrease the amount that you're
24 sneezing and, therefore, you can decrease the frequency and
25 maybe the severity of the leakage.

—Rosenzweig - Direct - Monsour—

1 Exercise in general, weight loss in general can
2 decrease not only the frequency and the severity but can also
3 make the, the condition less of a problem for the woman.

4 There are other things that can, that can be done which
5 are collectively called pelvic floor exercises. A lot of
6 women have been, are familiar with what's called Kegel
7 exercises. So, it's tightening up the muscles of the pelvic
8 floor that actually prevent the urine from going from the
9 bladder through the tube that you pee out of called the
10 urethra and actually comes out. So, those are the
11 non-surgical behavioral therapies.

12 There are some medicines that can increase the tone of
13 the muscles of the urethra. There -- there are some that we
14 use that might not have -- that we, we feel help but might not
15 be significantly proven in the medical literature. And then
16 the last option is surgery.

17 Q. Are there different types of surgery to treat stress
18 urinary incontinence?

19 A. Yes.

20 Q. And would you please explain those various types of
21 surgery to the ladies and gentlemen of the jury.

22 A. Well, there are basically three types of, of procedures
23 that have been shown to have probably the best effectiveness,
24 what we call efficacy.

25 One is the Burch procedure. And this is done through a

—Rosenzweig - Direct - Monsour—

1 small incision above the pubic bone. We don't need to go into
2 the inside cavity of the body where the bowel is and the other
3 internal organs. We stay above this investment that the body
4 has. It's call the perineum. It's like a cellophane layer
5 that protects the internal organs from rubbing against the
6 outside which contains muscles and bones and things like that.

7 So, we stay above that level called the perineum, use
8 some sutures to elevate the area that is shown to help hold
9 the urine back with increasing pressure in the abdomen. And
10 we bring those up to some of the strong ligaments in the
11 pelvis.

12 That can be done through, again, a small incision.
13 Yes, that usually requires a little bit longer surgery than
14 some of the others we're going to talk about, a slightly
15 longer hospitalization. And it does take a little bit longer
16 to recover from the operation.

17 Q. Let me ask you this, though. With regard to that
18 procedure, does that procedure result in any mesh being left
19 behind in a woman's body?

20 A. No. And, actually, there have been studies that have
21 looked at the question: Do you need to use a permanent suture
22 versus a suture that goes away with time, what's called an
23 absorbable suture? And it really doesn't matter for this
24 procedure. The success rate and the long-term outcome is
25 about the same whether you use a permanent suture or a suture

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1 that will go away with time.

2 Q. Okay. With regard to the slings that are mentioned
3 there, can you give us an idea of what those are?

4 A. There is something called the pubovaginal sling. And
5 that is an operation where you're placing a device -- and
6 this -- I'm using the term "devices" as a catch-all. You can
7 use a woman's own, what's called fascia. That's the strong
8 tissue that holds things together.

9 Tendons hold muscle to bone. Ligaments hold muscle to
10 muscle. And fascia -- they're all made out of the same thing
11 called connective tissue. Fascia invests muscles and kind of
12 holds the, the, a lot of the body together. So, it's kind of
13 the strong wrapping around muscle and sometimes around bone.

14 And, so, you can take this strong tissue called fascia
15 and use it as a loop that goes underneath the opening of the
16 bladder. And we call that the bladder neck. And that's what
17 goes from the bladder to the urethra. And this can help
18 stabilize that portion of the urethra so that it stops leaking
19 with coughing and sneezing.

20 That can also be done with a non- -- not using the
21 patient's own fascia, but can be used from a fascia that is
22 obtained by a cadaver. It can also be made out of fascia that
23 is obtained from a, from an animal source. That's usually
24 taking the animal's collagen, preparing it so we get rid of
25 all the extra foreign material, and just put the collagen

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1 together, or it can be used -- you can use a synthetic
2 material.

3 Q. Okay. And let's talk very briefly about the synthetic
4 materials because we'll get into that a little bit more later.
5 We've got the mid-urethral polypropylene slings, polypropylene
6 obviously not being a natural product or from a cadaver or
7 from an animal. Tell us what that procedure is and how it
8 differs, as briefly as you can, from the pubovaginal slings.

9 A. Well, basically, it's placed in the mid part of the
10 urethra instead of at the opening of the bladder into the
11 urethra. The idea is that that is another area that helps
12 promote the loss of urine so that when a woman coughs, this
13 stabilizes the middle part of the urethra so that there is a,
14 kind of a knee action that blocks urine from going out of the
15 urethra without actually blocking the urethra all the time.

16 Q. Okay. Now, here's one of the questions that I would like
17 you to answer for me. If the doctors of America did not have
18 the Obtryx sling to treat women with stress urinary
19 incontinence, would those women still have good, safe options?

20 A. That is correct.

21 Q. And they would include these top two procedures. Is that
22 a fair statement?

23 A. That is correct.

24 Q. And those are surgical options that they would have?

25 A. That is correct.

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1 Q. Now, let me ask you this today.

2 MR. MONSOUR: Ms. Blankenship, would you stand up.

3 (Pause)

4 MR. MONSOUR: And I'm only doing this because there's
5 four women and you've got to keep them straight at some point
6 in time.

7 So, Ms. Blankenship, okay, you can sit down now.

8 BY MR. MONSOUR:

9 Q. If Ms. Blankenship came to see you in April of 2009
10 when her Obtryx was implanted, what procedure would you
11 have done to treat her stress urinary incontinence?

12 A. My first line of treatment to treat stress urinary
13 incontinence is the Burch procedure.

14 Q. This one right here?

15 A. That is correct.

16 Q. Okay. It's a little longer surgery; correct?

17 A. That is correct.

18 Q. Slightly longer hospital stay?

19 A. That is correct.

20 Q. But no mesh is left behind?

21 A. That is correct.

22 Q. Now, have you done all three of these procedures?

23 A. Yes, I have.

24 Q. Okay. And how many surgical procedures have you done in
25 your career to treat stress urinary incontinence?

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1 A. Well over a thousand.

2 Q. Okay. And, first, how long have you been doing these
3 procedures? I should ask that first.

4 A. Well, I've been practicing close to 25 years.

5 Q. Okay. The Burch procedure that you've talked about, is
6 it still within the standard of care recognized as a valid
7 treatment for women like Ms. Blankenship?

8 A. That is correct.

9 Q. Okay. Has it been endorsed by various organizations as a
10 valid treatment?

11 A. That is correct.

12 Q. We heard a lot about organizations yesterday. Do
13 organizations still support the Burch procedure?

14 A. That is correct.

15 Q. What about pubovaginal slings?

16 A. That is also correct.

17 Q. So, if -- has the efficacy of the Burch procedure versus
18 the Obtryx -- let's focus on Obtryx first. Has the efficacy
19 of Burch versus Obtryx ever been looked at?

20 A. I haven't seen any studies that directly compare the
21 Burch procedure with the Obtryx mid-urethral sling.

22 Q. Okay. Have there ever been any studies that have looked
23 at the Burch procedure versus the, just any mid-urethral
24 sling --

25 A. Yes.

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1 Q. -- that's made out of polypropylene?

2 A. Yes.

3 Q. How did the Burch procedure stack up?

4 A. Well, there, there have been several long-term
5 prospective studies that have looked head-to-head between the
6 mid-urethral sling and the Burch procedure and they show an
7 equivalent efficacy, meaning, --

8 Q. Okay.

9 A. -- meaning effectiveness.

10 Q. All right. And let's break down, let's break down
11 medical treatments into two facets: Safety and efficacy.
12 Explain what efficacy means.

13 A. Efficacy is how well something works.

14 Q. Okay. So, that question is: Does the product cure what
15 it's intended to cure?

16 A. That is correct.

17 Q. What does safety mean with regard to a medical product
18 such as a mid-urethral sling?

19 A. What are the problems that can happen both in the
20 short-term and in the long-term associated with doing a
21 procedure, and also what you use to do the procedure; in this
22 case, a device.

23 Q. Why should women care about the safety of their products
24 if they're efficacious?

25 A. Well, everything -- every treatment that we do has some

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1 risks associated with it. In order for the person that is
2 agreeing to any treatment, they need to first know that it's
3 going to be helpful for the treatment that they're going to
4 have. But they also need to know what are the risks
5 associated with it so that the individual person can
6 determine: Are these risks something that I'm willing to
7 accept? Are these risks something that I can live with? How
8 frequently something happens, how severe something happens,
9 how long I might expect this complication to go on, and if I
10 do develop a complication, can it be treated.

11 Q. So, let me ask you this. Are each of these three
12 procedures efficacious at helping women with SUI?

13 A. Yes, that is correct.

14 Q. Does one of them have more long-term complications than
15 the others?

16 A. That is correct.

17 Q. Which one?

18 A. The mid-urethral slings made from polypropylene.

19 Q. Now, with regard to your Burch procedure that you
20 perform, do you ever see complications of long-term pain?

21 A. Obviously, every surgery has risks. Most of the risks
22 that we see from surgery are in the immediate post-operative
23 period. And what -- when I talk to a patient about the risks,
24 obviously I'm going to tell them that they're going to have
25 pain. They're going to have a risk of infection. They might

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1 have a risk of having difficulty emptying their bladder in the
2 short-term after a procedure.

3 Regarding long-term pain, it happens exceedingly rarely
4 with my Burch procedures.

5 Q. Okay. Have you treated women that have had mid-urethral
6 polypropylene slings implanted in them down the road years
7 after their surgery?

8 A. That is correct.

9 Q. In the long-term what are you seeing with those women?

10 A. Well, not only do I have from my clinical experience
11 dealing with these complications which I started to see in the
12 mid 2000s, so I've been seeing these patients for close to ten
13 years now. But also what we're seeing in the literature is
14 that there are a growing number of problems with polypropylene
15 mid-urethral slings that start to show up in a longer term
16 after the procedure than just the normal post-operative
17 period.

18 So, I'm seeing women that are coming in two, three,
19 four, five, six, seven years after the procedure with a new
20 problem that they didn't have before the procedure,
21 immediately during the procedure, and in what we would
22 consider the normal post-operative recovery time.

23 Q. And that's -- I guess that's what I'm getting at. Okay?
24 Most people have either had or know someone that's had a
25 surgery in their life. And following the surgery for a few

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1 weeks they're in pain and things hurt. Right?

2 A. That is correct.

3 Q. Then they heal up. What you're talking about is beyond
4 that time period?

5 A. That is correct. And it's important because we as
6 doctors when we do a procedure, we expect that a patient is
7 going to have problems and complications in the short-term and
8 immediate post-operative period. And, therefore, when
9 somebody is out six months, we've said, "Well, you're out past
10 that window that we would normally expect you to start having
11 problems."

12 What starting to see both in my clinical experience and
13 in the literature, that patients are starting to show up one
14 to five years after these procedures with problems. And, in
15 fact, the literature is even showing that 20 percent, or close
16 to 20 percent of women that have had mid-urethral
17 polypropylene slings are starting to develop the complications
18 more than five years out from the procedure.

19 Q. Twenty percent are developing problems five years after
20 the procedure?

21 A. That is correct.

22 Q. Is that -- would you categorize that as concerning or
23 alarming?

24 A. I would say that's alarming. And, again, this is a woman
25 that has figured that all of the risks that were discussed

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1 before surgery have now passed. And a lot of doctors might
2 assume that this might not be related to the surgery that I
3 did five, six, seven, ten years ago.

4 Q. If the rate is 20 percent at five years, what's it going
5 to be at ten?

6 A. Well, we don't know. And what has started to come out,
7 both from my clinical experience and the literature, is that
8 there is no time that we can say that someone that has had a
9 polypropylene mid-urethral sling is outside of the chance of
10 having a complication. There have been complications that
11 have been shown in the literature that have happened 17 years
12 after a mid-urethral sling was placed in a woman.

13 Q. Do you know what this is?

14 A. Yes, sir.

15 Q. What is it?

16 MR. MONSOUR: Can I approach, Your Honor?

17 THE COURT: Yes, sir.

18 THE WITNESS: Thank you. This is how a medical
19 device comes to us in the operating room. It's in a box
20 containing the medical device and another document that's
21 inside which is called the Directions for Use or Instructions
22 for Use. And this is the box that the Obtryx mid-urethral
23 sling comes in.

24 BY MR. MONSOUR:

25 Q. So, if we can break down the device, if we can

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1 break down the device -- and I think we have two of them
2 here. Okay? If you'll open yours and I'll kind of open
3 mine and we'll talk through them together.

4 You've never actually implanted an Obtryx. Is that a
5 fair statement?

6 A. That is correct.

7 Q. But you have implanted transobturator mid-urethral
8 slings?

9 A. That is correct.

10 Q. Okay. We will talk about how your use started with those
11 and how you stopped using those in a little bit. We will get
12 there. So, let's look at the package. We've got -- it comes
13 in a box and the package has -- I think Mr. Love walked
14 through this. It's got an instruction manual. Mine has two
15 Halo trocars.

16 A. That is correct.

17 Q. And I've got the mesh with the sleeve around it; right?

18 A. That is correct.

19 Q. What does yours have?

20 A. Well, I have a different kind of -- we call these trocars
21 or needles. And I'm going to -- we're going to show you a
22 video about how this is actually placed in a female. And this
23 has a sharp end to be able to pierce through the structures of
24 the inner leg and pop through a firm membrane called the
25 obturator membrane.

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1 It has that connective tissue, that fascia that I
2 talked about earlier. On each side is a muscle group. On the
3 vaginal side it's called the obturator internus, meaning
4 internal, muscle. And on the other side it has the obturator
5 externus, or external muscle.

6 Q. Okay. If you'd bring that one down here --

7 MR. MONSOUR: What we're going to do is we're going
8 to play a video, Your Honor, and -- we'd like to play a video.
9 Boston Scientific is aware of it. It is Boston Scientific's
10 own instruction video as to how to perform the surgery. It's
11 a little graphic, but it's only five minutes and 21 seconds
12 long. We will walk through it. We will freeze-frame and I
13 will have you diagram how the surgery is performed. Is it
14 okay if he steps down, Your Honor?

15 THE COURT: Any objection, counsel?

16 MR. ADAMS: With counsel's representation that this
17 is one of our videos, no objection.

18 THE COURT: All right, Doctor, you can step down.

19 MR. MONSOUR: If anyone gets queasy, raise your hand
20 and we'll stop. It is five minutes long. All right.

21 BY MR. MONSOUR:

22 Q. If you would -- here, you can use this to point
23 with.

24 THE WITNESS: Thank you.

25 MR. MONSOUR: All right, if we can start playing the

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1 video.

2 BY MR. MONSOUR:

3 Q. That's Boston Scientific, the Obtryx Transobturator
4 Mid-Urethral Sling System. That's -- that is what was
5 implanted in Ms. Blankenship; correct?

6 A. That is correct.

7 Q. And the other --

8 A. I'll try to talk up so -- I know we're close, but I'll
9 try to project so that you can hear me.

10 Q. Okay.

11 A. I'll try not to talk to the screen.

12 Q. And there's the trocar?

13 A. Right. We're seeing the different iterations of what the
14 trocars look like. And, again, this is used to pierce through
15 the tissue that I'm going to be showing you in just a minute.

16 Now, what we're looking for is a hole in the pelvic
17 bone called the obturator foramen. Foramen means window. And
18 you have to find that area. And we're looking for this area
19 right here, which is the sacral part of the window to place
20 this through.

21 We have nerves over here. It's call the obturator
22 nerve. There are blood vessels. We want to avoid those. We
23 don't want to injure the nerves or the blood vessels.
24 Obviously, if you injure a blood vessel, a patient could
25 bleed. If you injure a nerve, that can cause pain or actually

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1 numbness in the nerve.

2 Q. Okay. Now, real quick, just so it's clear for everyone,
3 there are two slings that are here. There's one that's kind
4 of more upright and there's one that's more horizontal. Which
5 sling are we talking about?

6 A. This is called a retropubic sling. It comes out above
7 the pubic bone. That's the bone that your belt sits on.
8 That's the diagram right here.

9 We're not talking about that sling today. We're
10 talking about this sling that goes underneath this bone right
11 here. That's the arch. That's an important bone because
12 that's where the baby comes through during a delivery. And
13 some women need to have C sections if these bones are too
14 close together because then the baby can't fit through.
15 There's a lot of studies that have shown that there is
16 differences between this arch and the size of this window
17 based on, on ethnicity.

18 Q. Okay. So, in the literature that might or might not come
19 up, we're going to be talking about two procedures in this
20 trial. This one would be called the TVT-O or the Obtryx
21 procedure; correct?

22 A. Correct. And this is what we're talking about with the
23 obturator approach going through this window called the
24 obturator foramen. And, so, if I, if I say transobturator or
25 obturator or TO, meaning transobturator, you all know what I'm

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1 talking about.

2 Q. Okay. And this is what we would call the TVT or the
3 retropubic one?

4 A. That is correct.

5 Q. Different approach, different surgery?

6 A. That is correct.

7 Q. All right. As I look in this obturator hole in the bone,
8 I see a lot of things going through it. What is present in
9 that obturator hole?

10 A. Well, this nerve right here is called the obturator nerve
11 and it innervates your inner leg here. And that's very
12 important for you to be able to walk.

13 Q. All right.

14 A. There's also blood vessels here that are in red. The
15 veins are in blue. And there actually is a much larger vessel
16 that comes down a little bit further out, but we're going to
17 just concentrate on these for right now.

18 Q. Okay. So, if we can, let's talk about the -- before we
19 show the surgery, I want you to kind of give an idea with this
20 diagram and with this and with that trocar give us an idea of
21 how it would go in. And then they can see it, not real-time
22 but close to real-time.

23 A. What we first do is we identify this area. There's a
24 long muscle of your leg called the adductor longus. And that
25 muscle is important for you to be able to bring your legs

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1 together. Adduction means bringing the legs together.

2 And where the tendons -- it's this bone right here.

3 You rock your finger -- you'll see this in the diagram.

4 You'll be able to identify this specific area. So, you'll see
5 the surgeon make a little X there.

6 There will be a hole put right here. There will be a
7 cut in the vagina. This is supposed to go in the mid part of
8 the urethra. The average woman's length of the urethra after
9 having had babies is about three sonometers. It's
10 centimeters, but I had a professor that spoke in sonometers
11 and it just kind of clicked. So, I apologize if it's
12 centimeters, but I will try to not go back to my old way of
13 saying it.

14 So, we make an incision in the vagina. It's about one
15 centimeter below the opening of the urethra which is called
16 the urethral meatus, meaning opening. There is an incision
17 that's made, maybe one to three sonometers, inside the vagina.
18 And then it's tunneled out to try to get as close to that
19 muscle that I talked about on the inside of the obturator
20 foramen called the obturator internus muscle.

21 From the outside, this passer is placed, curved, and
22 then brought out through the inside of the vagina. There's a
23 little hook here and there's a little loop here. This is
24 actually hooked onto that and brought out through the hole.

25 Now, you can see that this is a pretty small little

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1 hole and this is a fairly wide piece of tape. On average,
2 this is a little bit over a centimeter wide.

3 There's a little dilator here that makes this hole a
4 little bit bigger so that this will get through without a
5 problem.

6 Q. Okay. Is that one of the concerns as this goes through
7 the -- that it could get crinkled up?

8 A. Well, we're taking a flat piece of tape, trying to put it
9 through a round hole. What can happen -- and, remember, the
10 surgeon can only see this small little window that he's making
11 inside the vagina. The rest of this procedure, as you'll see
12 in the video, the surgeon is blind to what is actually
13 happening there.

14 When this is all done, you can only see the small
15 window of the tape. There's all this other tape out here that
16 we can't see.

17 Q. So, let me ask you this. So, when this goes through --
18 when I'm the doctor and I punch this through here, do I know
19 as I punch it through there whether I've hit nerves or not?

20 A. No. However, when the -- there are several things that
21 can be done to help minimize the risk. And this has been
22 shown in anatomic studies where they take cadavers and they
23 put them in different, legs in different positions and then
24 actually watch these trocars go through and to see how close
25 you actually get to the nerves.

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1 And when I'm illustrating the video, there's a way to
2 bring the legs back so that the knee is actually pointed
3 towards the head that moves this nerve further away. So, it's
4 very important to get this hip right here flexed to a certain
5 level so that you avoid the nerve injury.

6 Q. Okay. So, let's keep, let's keep going. You do, you do
7 the trocars through and then you what?

8 A. Then you advance the tape through the hole that was
9 created so that it gets into the position where this is then
10 the mid part of the urethra.

11 Q. Okay. And then what do you do?

12 A. Well, you cut the tab to remove the tab. And that opens
13 up -- it actually separates these two ends of the sheath.
14 This comes off and then you have the sheath, this outer
15 envelope or sheath that can then be removed.

16 And we'll show on the video that is a very important
17 part of the procedure removing this. And there have been
18 studies that have shown that if you need to pull real hard to
19 get the sheath off, you can actually see the tape stretching.
20 And there have been studies that have been done to say how
21 much stretch actually permanently damages the tape.

22 You see every time I stretch it, there are little
23 flakes that come off. And these edges right here start to
24 crinkle, what we call fray. It's like wearing a pair of jeans
25 for a long time and the ends of the blue jeans that have been

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1 rubbing on the concrete start to fray. You see strands that
2 are starting to come out.

3 So, pressure on this will cause it not to bounce back
4 to its normal position. Edges, as you can probably see, those
5 little white things that are coming off, that's the actual
6 part of the tape that is coming off as particle loss. We call
7 that flaking.

8 Q. Okay, all right. So, you have now pulled the sleeves
9 off. And what, what's the next step?

10 A. Well, the final step is to do what's called adjust the
11 tension. These devices are supposed to go in tension-free.

12 Q. Why?

13 A. Well, it's been shown that if you put it under tension,
14 you increase the risks associated with it. The first risk you
15 might see is that the patient won't be able to urinate or void
16 or pee. So, if I use either of those terms, you know what I'm
17 talking about.

18 The other thing is that if it's under tension, it can
19 actually make its way through the vaginal tissue and cause
20 what's called a vaginal erosion, or the mesh is extruded or
21 exposed.

22 Q. All right. Let's walk through the rest of the video.

23 A. All right. So, this is the bone structures that we're
24 talking about which are called the inferior pubic, which is
25 this area here, ramus, which means arm. This here is the bone

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1 that you sit on.

2 Now we have a catheter in the woman's urethra which is
3 right here. The doctor is feeling for that adductor longest
4 tendon and is finding that little notch and making an X right
5 there. So, that's the point where we're going to be going
6 through.

7 And, again, it's fairly easy to find that, that portion
8 by feeling for that tendon, rocking your finger and the tip of
9 your thumb, and your thumb will hit that exact portion, that
10 exact point right there.

11 Q. Okay. It says here the distance between the needle entry
12 point and the obturator canal is estimated to be three to
13 five centimeters.

14 A. Well, what they're talking about, this entry point and
15 this nerve right here. And, yes, if the legs are in the ideal
16 position, if this bone right here is in its average
17 angulation, this nerve will be at or around this distance.

18 However, there have been studies done, again on
19 cadavers, that have looked at if you change the way the legs
20 are, there is a difference in these bones' narrowness. And if
21 there's a difference in the opening of this window, that nerve
22 actually does get, ends up being closer to where the tape goes
23 through.

24 Q. Okay. Let me ask it this way. Is that another way of
25 saying that this is a one-size-fits-all surgery in a

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1 not-all-one-size-fits-all world?

2 A. That is correct.

3 Q. Okay. Now, what's this showing?

4 A. This is showing the other sling that we talked about that
5 comes out above the pubic bone.

6 Q. Sometimes referred to as the TVT?

7 A. That is correct, or the retropubic, behind the pubic
8 bone, mid-urethral sling.

9 Q. Okay. And then this is showing the Obtryx,
10 transobturator?

11 A. That is correct. We talked about the various trocars or
12 needles, the various configurations. One is a curved. This
13 one is what's called a helical. So, the surgeon has the
14 opportunity to decide which one of these needle devices
15 they're going to use.

16 So, now the surgeon is going to be making the incision
17 in the front wall of the vagina. And, again, I apologize.
18 This is going to be the start where it becomes a little bit
19 more graphic.

20 This is the incision that's made in the front wall of
21 the vagina. The doctor is taking a pair of surgical scissors
22 and cutting between the vaginal wall and the deep tissue of
23 the vagina to create the plane for the needle to come through,
24 making a stab wound in the inner thigh. And now it's going to
25 pass the needle from the inner thigh through the vagina.

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1 On average, this needle is going through four muscle
2 groups.

3 Q. Okay. I have a quick question. I've watched this video
4 before. As they're pushing the video -- as they're pushing
5 the trocar through the tissue, I notice there's kind of a pop.
6 What is that?

7 A. Well, that is where it's actually going through those two
8 muscle groups that I talked about, the obturator internus, the
9 obturator externus, and that fascial window. So, those are
10 two of the muscle groups that the tape is going through.

11 The other two muscle groups are in the inner thigh. It
12 can go through the adductor brevis, which is one of the
13 smaller muscles that help work your legs, and the gracilis
14 muscle that kind of drapes down along the inner thigh.

15 Q. Okay. The fascia, can you give us an idea of what the
16 fascia is again?

17 A. Well, what we've talked about is fascia invests
18 something. It's a protection. I talked about the cellophane
19 on the inner wall that kind of holds all the bowels in and
20 allows them to move around smoothly.

21 This is thicker than that. It's more heavy. It's kind
22 of like the gristle on a piece of steak. And, so, you can
23 feel that if you're trying to cut through that. There's some
24 meat to that.

25 Q. So, it's tougher?

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1 A. It is much tougher, yes.

2 Q. Okay.

3 A. You'll see this is going through the inner thigh. And
4 now we're seeing that there is some force that needs to be
5 directed to the needle to get it to go through the muscle
6 groups and the fascial window you saw right there, that pop.

7 So, there was the force that needed to be taken. Bring
8 it out through the incision that was made inside the vagina.
9 You hook the little loop I showed you inside the end of the
10 needle. And then it's brought through.

11 Now, as you see, there's a little bit of force that it
12 needs to take to get this big piece of tape through the small
13 opening that was made by the needle. That puts tension on the
14 tape. It puts tension on the outer sleeve. But the tape is
15 inside the outer sleeve and it's going to put tension on that
16 area too.

17 Now, the other side is being brought --

18 Q. I think this is actually a different trocar.

19 A. That is correct. This is the curved trocar. And there
20 is a pop and it's going through muscle, the fascia.

21 Now what's happening is what's called a cytoscopy where
22 a device called a telescope is being placed through the
23 urethra into the bladder to look at both of the structures to
24 make sure that nothing has been injured.

25 Now the device is being seated into its proper

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1 location. An instrument is being placed behind it to help
2 when the sheaths are coming off not to put any tension on the
3 tape.

4 Q. Now, why don't you want tension again? Because it will
5 cause the fraying?

6 A. Well, that's one of the things that can cause the
7 fraying. It can cause -- when the sheaths are coming off,
8 you're putting tension on that. You can get fraying. You can
9 get the sling itself to deform or change its shape, or it can
10 end up being placed with too much tension. And we talked
11 about before that can lead to, in the short term, problems
12 such as difficulty emptying or working its way into the
13 vagina.

14 Q. Okay.

15 A. We're going to talk about a different phenomenon later on
16 which meets the longer term problems associated with this
17 actually contracting and shrinking.

18 Now, you see that you need a little bit of force to
19 take off the outer sheaths. And there have been studies that
20 have actually looked at that as being a very critical portion
21 of this procedure to get the sheaths off without putting a lot
22 of pull on it to get it out through the hole.

23 Q. Okay. What are they doing here?

24 A. Right now they're cutting the excess tape off. This is
25 about 40 to 50 centimeters long. When it's all done, about 15

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1 centimeters is left inside the body.

2 Q. Okay. So, if you'll hold that up again. So, if we hear
3 about somebody having a small portion of their mesh removed,
4 the remainder of this would still be inside the body?

5 A. That is correct.

6 Q. Okay.

7 A. So, the excess is cut. These small holes are closed off.
8 And then suture material is used to close up the vagina.

9 Q. And then there's one last slide. There's one last little
10 portion here I want to see. And it says here -- it says,
11 "Refer to package insert provided with product for complete
12 Instructions for Use, including indications for use,
13 contraindications, potential complications, warnings and
14 cautions."

15 Is that correct?

16 A. That is correct.

17 Q. And that's this. And that is this that we looked at
18 right here, the Instructions or Directions for Use?

19 A. Yes.

20 Q. Okay, all right. You can take your seat.

21 A. Thank you. Your Honor, may I approach?

22 THE COURT: Yes, sir.

23 BY MR. MONSOUR:

24 Q. So, have you ever used a polypropylene sling to
25 treat a woman for stress urinary incontinence?

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1 A. Yes, I have.

2 Q. Okay. When did you first do it?

3 A. Around 2003 I started using the retropubic polypropylene
4 mid-urethral slings.

5 Q. So, 2003. And did you ever start using the
6 transobturator slings kind of like we just saw?

7 A. Yes. I was invited to go to Belgium and work with one of
8 the inventors of a transobturator sling. I spent three days
9 there doing lectures, cadaver dissections, and actually
10 placing two of the obturator slings in live patients.

11 Q. And when was that?

12 A. That was in October of 2004.

13 Q. And the man that you learned from in Belgium with regard
14 to transobturator slings, he's pretty highly regarded in that
15 world?

16 A. That is correct.

17 Q. Would, would you say that with regard to these types of
18 slings you got some of the best training in the world?

19 A. That is correct.

20 Q. So, you started using them in 2003 and 2004. Why are you
21 here?

22 A. Well, I stopped using mid-urethral polypropylene slings
23 in approximately 2006 to 2007.

24 Q. And why did you stop using polypropylene mid-urethral
25 slings after using them for about three years?

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1 A. I started seeing patients that were referred to me with
2 mid-urethral polypropylene slings that were having
3 life-altering, life-changing complications.

4 Q. And you were able to figure this out by implanting women
5 and following them for three years?

6 A. That is correct.

7 Q. But did you also get some referrals from some other
8 people too?

9 A. That is correct. As I stated earlier, I, I had run a
10 residency program where I trained ten residents a year for
11 seven years. Most of those residents stayed in the City of
12 Chicago and still referred me their patients. And, so, I had
13 had a lot of patients being referred to me that started to
14 have problems.

15 Q. So, what was it about seeing these patients that got you
16 to change your mind on using polypropylene slings?

17 A. I wasn't seeing the extent, severity, and difficulty
18 treating these complications with the other surgical
19 procedures that I had been doing to treat stress urinary
20 incontinence.

21 Q. Okay. Have you ever implanted a Boston Scientific sling,
22 whether it was retropubic or transobturator?

23 A. No, I have not.

24 Q. Okay. Now, you talk about the complications that are
25 associated with these slings. Give the jury an idea of the

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1 complications that you've seen clinically with women that have
2 come to see you that have had these slings implanted in them.
3 A. The clinical complaints they come in with are difficulty
4 emptying their bladder, what we call voiding dysfunction;
5 difficulty emptying their bladder completely, which is called
6 urinary retention; pain; pain walking; pain in the pelvis;
7 pain having intercourse; that the mesh actually worked its way
8 through the vagina, the vaginal tissue that you saw in the
9 video that the doctor was closing, and now you see this
10 polypropylene mesh inside the vagina; patients that now have
11 what's called an over-active bladder where they have to go to
12 the bathroom frequently and urgently.

13 They have what's called irritative voiding symptoms
14 where they have discomfort and they always feel like there's
15 something in their bladder that they have to, to urinate even
16 though their bladder is empty, and also a recurrence of their
17 leaking which was worse than it was before.

18 Q. One of the things you mentioned was nerve and muscle
19 damage. Can you give us an idea of why a procedure like the
20 Obtryx would cause nerve and muscle damage?

21 MR. ADAMS: Objection, Your Honor. May we approach?

22 THE COURT: Yes, sir.

23 (The following occurred at sidebar.)

24 MR. ADAMS: I should have objected to this before
25 when he was talking about nerve damage. There's no issue in

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1 this case that Ms. Blankenship, who is the woman who he's here
2 to testify about, she doesn't have any nerve damage. And he's
3 admitted to that. So, Judge Goodwin was very specific saying
4 that they shouldn't be talking about complications that are
5 not at issue with the plaintiff that they're responsible for.

6 MR. MONSOUR: Except for the fact that other women do
7 have nerve damage, and he's our general causation expert and
8 we're allowed to talk about the complications that these women
9 have.

10 MR. ADAMS: Judge Goodwin said it's limited to
11 complications this woman has.

12 THE COURT: Okay. My recollection, counsel, on that
13 particular motion *in limine* may not be consistent with yours.

14 I find, counsel, that this falls under the motion *in*
15 *limine* that was filed to preclude any evidence or argument
16 that the pelvic mesh can cause complications not experienced
17 by the plaintiffs. The Court granted that motion. So, my
18 review is not consistent with what you believe the Court's
19 position to have been, Mr. Monsour.

20 MR. MONSOUR: Well, the -- it's all -- it's kind of
21 all tied together, Your Honor. It's the -- there is shrinkage
22 and then there's the nerves that go in. The nerves are what
23 generate the pain. And all these women have been talking
24 about pain. Well, to have pain, you have to have nerves that
25 transfer the pain. So, they're allowed to talk about chronic

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1 pain. And you can't have transfer of the nerve -- of the pain
2 sensation without a nerve.

3 THE COURT: They have all indicated -- I agree with
4 you that they suffered pain. He can certainly testify to
5 that. But to those complications or, for lack of a better way
6 of putting it, injuries that might have resulted that these
7 women did not suffer I'm going to preclude as consistent with
8 the Court's order.

9 MR. MONSOUR: Okay.

10 MR. ADAMS: The other issue is the only, the only
11 explanation that he has given for Ms. Blankenship's
12 problems -- and, again, that's the only woman who he's
13 addressing -- is shrinkage of the mesh. He hasn't talked
14 about the other things that are on the slide.

15 And, so, I think counsel -- I should have objected to
16 that earlier. I think counsel should only be talking about
17 whatever his opinions are on shrinkage.

18 MR. MONSOUR: Shrinkage, degradation, pain. I mean,
19 they're all kind of related. It contracts. I mean, he talks
20 about voiding dysfunction. To try and draw you a picture,
21 you've got the urethra, and the voiding dysfunction is caused
22 by the shrinkage of the sling rising up and pinching off the,
23 the urethra and causing the problem. So, when you say
24 shrinkage or contracture, it's all interrelated.

25 And then the pain comes from when you cut the sling

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1 where the sling is still, it's up in the obturator area where
2 there are all those nerves. And what is going on, as it
3 shrinks and contracts it's pulling on those nerves. And
4 that's why she has pain.

5 So, it all falls under this shrinkage, contraction.
6 It's all, it's all related. It's all a part of one process.

7 THE COURT: I'm not trying -- I will not preclude you
8 from inquiring of him about the pain that they experienced or
9 the genesis of that pain. I'm not going to preclude you from
10 discussing with him the shrinkage and the degradation. I
11 think it's clear from the Court's ruling that he's going to do
12 that. But any type of complication that they did not
13 experience is, in fact, precluded.

14 MR. ADAMS: And that includes nerve injury. There's
15 no evidence she has nerve injury.

16 THE COURT: Well, in my opinion, gentlemen, there's a
17 difference between nerve injury and a nerve being pulled which
18 results in pain which is the so-called injury in this case.

19 MR. MONSOUR: Let me clarify that with him then.

20 THE COURT: All right. You understand my ruling?

21 MR. MONSOUR: I, I --

22 THE COURT: There is a distinction, in my opinion,
23 between nerve injury, which there is no indication that these
24 people, any of them suffered, and what might be related to
25 nerves that cause the pain, which it's clear that they've all

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1 indicated that they suffered.

2 MR. MONSOUR: Okay. I got you.

3 THE COURT: All right.

4 (Sidebar concluded.)

5 BY MR. MONSOUR:

6 Q. To clarify my questions from here going forward,
7 when I talk about any sort of nerve issues, what I'm
8 limiting it to, just so it's fair to you and the jury,
9 I'm limiting my questions to the pain that results from
10 the contraction or the shrinkage or the degradation.
11 Okay?

12 A. I understand that.

13 Q. Okay. Now, the -- a couple of the things that you
14 mentioned, and I -- some of the things that you mentioned
15 about the problems that we have with this product that you've
16 seen is you've mentioned that it's, it's tough to get it out.
17 It's difficult to remove the product.

18 A. This is correct.

19 Q. Why is it difficult to remove these products?

20 A. Well, there are a variety of things. First is the
21 location that it's placed. The inner thigh has -- and I
22 described during the video that the mesh is going through four
23 muscle groups. To try to dig the mesh out of muscle is very,
24 very difficult. The area where the muscles, that the tape is
25 in the inner thigh is an area that has very large blood

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1 vessels and nerves.

2 But there's a process that takes place after this
3 polypropylene mesh is placed inside the vagina which
4 contributes to the difficulty in removing the mesh. And what
5 we have here is a description of the four main problems that
6 take place with the mesh.

7 The mesh degrades, meaning that it gets hard. It gets
8 brittle, and it cracks.

9 Q. Now, let me interrupt you there. How do you know that it
10 gets hard, it gets brittle, and that it cracks? How do you
11 know that?

12 A. Not only have I seen this when I have to take the mesh
13 out, but it is very well documented in the medical literature.

14 Q. Okay. So, as you -- you've seen it physically during a
15 surgery?

16 A. That is correct.

17 Q. Okay, shrinkage. Tell us what is shrinkage?

18 A. I think everyone is aware of if you take a wool sweater,
19 you put it in the dryer, it goes in extra large, it comes out
20 extra small.

21 What happens with this product is that it sets up a
22 reaction that the body is trying to either get rid of this
23 foreign body, or at least wall it off if you can't get rid of
24 it. It's called the chronic foreign body reaction.

25 In response to that, there are some blood cells. The

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1 first responder cells are the white blood cells. They go in
2 and they try to get rid of something that's invading the body,
3 whether it's a bacteria or a splinter. The bacteria tries to
4 kill the splinter. It tries to wall it off.

5 And, so, what happens is these blood cells come
6 together and they form what's called a multinucleated giant
7 cell, which is the white blood cells that come together and
8 try to wall off the individual fibers of the polypropylene
9 from the rest of the body.

10 If those things grow together, there's no way that any
11 tissue can get in there. And then scar wraps around the whole
12 piece of tape. And that's called a scar plate.

13 As that scar gets older, it contracts. And, therefore,
14 it causes the mesh to become less wide and less long, which we
15 describe as contraction or shrinkage.

16 Q. Okay. Is contraction and shrinkage a significant problem
17 for products like the Obtryx?

18 A. Yes. And as I described during the video that we saw,
19 the idea is that this is supposed to be placed tension-free.
20 And we talked about the importance when we're doing the
21 procedure, making sure that the device is not under tension
22 when we're done with the procedure.

23 Unfortunately, if contraction and shrinkage takes
24 place, it's then going to put the device under tension. And,
25 therefore, as I talked about how several years after the

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1 device is placed we start to see new problems that showed up
2 that weren't a problem in the immediate post-operative period.

3 And the reason for that is the device is degrading.
4 The device is contracting and shrinking. There's a chronic
5 foreign body reaction where studies have shown doesn't go
6 away. It's always going to be there, which means that this
7 process is then going to start itself all over again so that
8 there is no time when the device will be, will stop degrading.
9 There is no time where the device will stop contracting and
10 shrinking. And there is no time where this chronic foreign
11 body reaction will stop.

12 Along with that chronic foreign body reaction is a
13 process of inflammation. If you cut yourself or you burn
14 yourself, the area where the cut is undergoes changes, but the
15 area around it turns red. And red is a sign of inflammation.
16 It's the body's way of getting more blood into that area to
17 help the body heal.

18 Now, I talked about the first responders that are the
19 white blood cells. The next thing the body does in the
20 long-term is that it sends a send tree out to say, "What's
21 going on with this area of irritation and damage?" And that
22 sensory is the nerves.

23 And it's been shown that nerves start growing towards
24 the mesh and actually gets inside the little holes of the mesh
25 which are called pores. And nerves grow up to the mesh and it

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1 hits that plate of scarring that I described for you a few
2 minutes ago, and it creates a little tuber of nerves called a
3 neuroma.

4 And when I was asked what happens when the mesh is
5 taken out is, well, the nerves that have grown through it get
6 cut. The nerves that have grown up against it get cut. And
7 either they immediately start creating pain or then the nerve
8 could go to sleep. When it wakes up, it's now ready to
9 transmit the signal of pain.

10 Q. Okay. So, let me ask you this.

11 Can I see the sling? May I approach, Your Honor?

12 THE COURT: Yes, sir.

13 BY MR. MONSOUR:

14 Q. If I look at this sling, there's a lot of little
15 holes in the sling; right?

16 A. That is correct.

17 Q. If, if this -- if tissue grows into those holes, scar
18 tissue grows through those holes, is that what holds it in
19 place?

20 A. Well, the idea is that normal tissue, blood cells, and
21 fat cells are going to grow into those little pores. The pore
22 size of this product is about a millimeter.

23 It's been shown that if the pore size is around that
24 size, it doesn't allow good tissue to grow into it. It lets
25 those things that I talked about before, the granulomas from

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1 the chronic foreign body reaction --

2 MR. ADAMS: Objection, Your Honor. May we approach?

3 THE COURT: Yes, sir.

4 (The following occurred at sidebar.)

5 MR. ADAMS: This is -- again, this is not a
6 permissible general causation opinion. There is -- he's
7 offered no opinions in his report about the impact of pore
8 size. He hasn't even examined our mesh. There's no evidence
9 that he has an opinion either in his report or his deposition
10 that pore size has anything to do with Ms. Blankenship. So,
11 the question is why is he talking about it? He shouldn't be.

12 MR. MONSOUR: All I was trying to get at, Your Honor,
13 was how it's difficult to cut it out because Ms. Blankenship
14 had a very tough procedure to try and cut it out. I can ask
15 him not to go into the pore size issue.

16 THE COURT: I'm going to sustain the objection to the
17 substance that's been raised by Mr. Adams and if you can
18 rephrase --

19 MR. MONSOUR: Sure.

20 THE COURT: -- and direct him even with a leading
21 question to avoid the area and get to where we need to be.

22 MR. MONSOUR: Gotcha. Thank you.

23 THE COURT: I want to preserve the plaintiffs'
24 objection and exception.

25 (Sidebar concluded.)

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1 BY MR. MONSOUR:

2 Q. What I'd like to focus on, Dr. Rosenzweig, is not
3 so much the issue of adequacy of the pore size but more
4 once -- in explaining to the ladies and gentlemen of the
5 jury that how, whether there's scar tissue in-growth or
6 natural tissue in-growth, why that makes removing
7 something like this so difficult when it's not that hard
8 to put in. Why is it so much more difficult? Is it
9 because of the tissue in-growth?

10 A. Well, it's because of the scarring around it and also the
11 location where the mesh is.

12 Q. Is, is it more difficult to cut something like this out
13 of scar tissue once it's degraded and shrunk and deformed?

14 A. That is correct.

15 Q. And why is that?

16 A. Because the body has enveloped it. It's created
17 attachments outside of the normal position where the mesh is.
18 And that becomes very, very difficult to take out.

19 Q. Okay. Approximately how many times in your career have
20 you attempted to take out one of these when they've degraded,
21 shrunk, deformed, and caused the woman problems?

22 A. I've done close to 300 removal procedures which are
23 called explant procedures.

24 Q. Okay. When you do an explant, do you get all this out?

25 A. It is exceedingly difficult to get, with the obturator

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1 sling, the mesh out of the vaginal portion of the vagina, let
2 alone trying to dig it out of the inner thigh.

3 Q. Okay. Is it a fair statement to say that when attempting
4 to remove transvaginal mesh the doctors never get it all out?

5 A. I would say that it is exceedingly unlikely, from both my
6 clinical experience and review of the literature, to get all
7 the mesh out.

8 Q. In Jean Blankenship's case, this was used. They cut,
9 let's say, off to about here, the 15 sonometers. Her doctor
10 did a revision. What part did he cut out?

11 A. He tried to cut the middle portion of the sling in the
12 urethra to separate it in the middle.

13 Q. So, someone like Jeanie Blankenship, if they moved out
14 this little middle portion right here -- is that fair?

15 A. That is correct.

16 Q. So, the rest of this still is inside her today?

17 A. That is correct.

18 Q. Now, when you remove this small middle part, does that
19 stop the foreign body reaction, the shrinkage, and the
20 deformation? Does that stop that from occurring on the rest
21 of the sling?

22 A. No, it doesn't. And, actually, what can happen is --
23 because now you've re-exposed the mesh to bacteria, that
24 process can start all over again.

25 Q. So, what is the outlook for women that still have this

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1 inside of them even if they've had a surgery?

2 A. Well, the processes that we have outlined up there don't
3 stop. They will continue through the life that the, of the
4 mesh inside of a woman.

5 On average, we're looking at 35 years that these
6 products are going to be in a woman's body. And these
7 processes are going to continue, and the problems that they
8 create, the pain, the difficulty voiding, the pain with
9 intercourse, the problems with irritation, with peeing, and
10 the others that we've talked about are going to continue.

11 Q. Okay. So, let me ask you this. A woman comes to see
12 you. She went to see another doctor. He put a sling in her.
13 He can't fix it. You're the guy in Chicago that they send the
14 problem people to. You attempt to remove the sling but you
15 can't get all the mesh out. You can only get out a little bit
16 like in Ms. Blankenship's case. And the woman is still having
17 problems. In that situation, what do you do to try and help
18 her?

19 A. Well, there are a number of non-surgical things that we
20 can do. There are medications that can be placed inside the
21 vagina, a suppository, a Valium which is a nerve modulator and
22 a muscle relaxant. There is physical therapy to try to ease
23 the problems that the muscles are having with where the mesh
24 is going through.

25 There are nerve blocks which can block the nerves that

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1 are supplying the vagina to try to decrease or mitigate the
2 pain that a woman is having, the pain with intercourse.

3 And, finally, blocking what's called a trigger point.
4 The mesh is going through a muscle. And that, that becomes a
5 fulcrum of pain that spreads out through the muscle and will
6 cause the pelvic floor muscles to spasm. And that's been
7 described in Jeanie Blankenship currently, that she's got
8 spasm of her pelvic floor muscles.

9 Where the mesh is going through the muscle is often a
10 trigger point, the fulcrum, the epicenter of that wave of
11 muscle spasm that causes pain. And that point can be injected
12 with medication to relieve it as a trigger point.

13 Q. Okay. Do long-term -- do the women that have mesh inside
14 of them that have had complications, the women that have the
15 problems that are seeing doctors like you, how do they do
16 long-term?

17 A. Well, even with the removal operation to treat difficulty
18 voiding, pain, pain with intercourse, there are a group of
19 women, and I would say from the literature and my clinical
20 experience about 20 percent don't get better. About another
21 20 -- 40 percent get improved, but that improvement can be
22 anywhere from a little bit to a lot. And, actually, only
23 40 percent actually get better where they're not having a
24 problem.

25 Q. So, if we look over at Ms. Blankenship right now and she

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1 has already had surgery to put it in. She's already had the
2 surgery to try and fix it. She's not better. How long can
3 someone like Jeanie hope to deal with these problems?

4 A. Well, as I stated before, the causes of the problems that
5 Jeanie Blankenship was having are going to continue. The
6 degradation, the contraction, the chronic foreign body
7 reaction, chronic inflammation are going to continue. And,
8 therefore, that is what's leading to the discomfort that she's
9 having and that will continue.

10 Q. All right. I want to talk to you specifically about
11 shrinkage.

12 THE COURT: Counsel, before you move to a different
13 area, would this be a good time for a break?

14 MR. MONSOUR: Yes, it would, Your Honor.

15 THE COURT: Ladies and gentlemen of the jury, I'm
16 going to give you a recess. While you're out, do not discuss
17 this case among yourselves or permit anyone to discuss it with
18 you or in your presence. And please be in your jury lounge at
19 10 minutes till the hour. We'll stand in recess.

20 (A recess was taken from 10:33 a.m. until 10:51 a.m.)

21 (The Jury entered the courtroom at 10:51 a.m.)

22 COURT SERVICES OFFICER: All rise.

23 THE COURT: Mr. Monsour.

24 MR. MONSOUR: Thank you, Your Honor.

25 BY MR. MONSOUR:

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1 Q. I want to talk to you now about shrinkage of the mesh,
2 but I want to talk about it in a different angle.

3 If I look at the how-to booklet that we got out of our
4 box, and if we look at the video, one of the things that the
5 video stressed and that the instruction manual stressed, on
6 Page 4, it said, "The user should note the importance of
7 placing the mesh without tension under the mid-urethra."

8 Okay?

9 A. Yes.

10 Q. All right. So here's my question. This is a tricky one.
11 If you put the mesh in without tension and you do it right,
12 but down the road it shrinks and contracts, isn't that going
13 to cause tension?

14 A. That is correct.

15 Q. So how is a doctor supposed to put this in without
16 tension if the product over time shrinks?

17 A. Well, since we don't know how quickly it shrinks, we
18 don't know to the extent that it shrinks, it would be very
19 difficult, if not impossible, to be able to put it in in the
20 manner where it will stay tension-free for the rest of a
21 woman's life.

22 Q. Well, if it shrinks, shouldn't they tell the doctors in
23 here that it shrinks, if they know it?

24 MR. ADAMS: Objection, Your Honor, with respect to
25 opinions about the DFU. May we approach just briefly?

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1 THE COURT: If you need to.

2 (The following occurred at sidebar.)

3 MR. ADAMS: Again, he offered no opinions in his
4 report critical of the DFU. Judge Goodwin didn't discuss this
5 as a general causation opinion. He's not a warnings expert.
6 It's an opinion -- it's a whole area of opinions that were not
7 disclosed.

8 THE COURT: Mr. Monsour, the question was shouldn't
9 that be in this statement --

10 MR. MONSOUR: Yes.

11 THE COURT: -- prior to the objection. In other
12 words, let me say to you that it is definitely a criticism of
13 the DFU.

14 MR. MONSOUR: Well, it is, but I can ask him if a
15 physician like him would need that information to implant it
16 and wouldn't he expect it, and if that information was in the
17 DFU, couldn't he have relied upon that to gather that
18 information?

19 THE COURT: That's the same criticism, if it's not in
20 there, for you to ask if it's in there and if it would have
21 been helpful to him and if he would have relied upon it.

22 MR. MONSOUR: Okay.

23 THE COURT: It's still a criticism of it not being
24 there.

25 I have reviewed again the judge's ruling with respect

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1 to this doctor's testimony. I've also reviewed for the first
2 time his expert report and there are no such criticisms.

3 I've also listened carefully to his testimony thus
4 far and I don't find that to be one of those opinions that's
5 necessary in order to get to one of the disclosed opinions.

6 MR. MONSOUR: Okay.

7 THE COURT: Excuse me.

8 MR. MONSOUR: Can I ask him this, since he is a
9 medical expert --

10 THE COURT: I'm sorry.

11 MR. MONSOUR: That's all right.

12 THE COURT: Excuse me.

13 MR. MONSOUR: Not in a criticizing way, but can I
14 just ask him if the DFU contains a warning of shrinkage and
15 contracture, if it is in here? That's not a criticism.

16 THE COURT: You can, you can ask that question.

17 MR. MONSOUR: Okay.

18 THE COURT: Because I think that you are permitted to
19 get into that issue. But as to whether or not he would expect
20 it to be there or it's necessary or whether or not it would
21 have been helpful to him to be there, I find that those are
22 criticisms.

23 MR. MONSOUR: I gotcha.

24 MR. ADAMS: Can we just -- I guess short-circuit it.
25 I don't want to keep interrupting, but, as you see,

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1 Mr. Monsour is pretty persistent about coming back to things.
2 I think it's clear there was no opinions that should come in
3 on the DFU, so do you plan on going at it, banging on this
4 issue more than just asking him that question?

5 MR. MONSOUR: I don't think so.

6 MR. ADAMS: Okay.

7 THE COURT: Just so the record is clear, I'm
8 preserving your objection and exception. I'm going to
9 preclude opinions criticizing the content of the DFU. Those
10 opinions have not been previously disclosed, and I think that
11 any response is sufficient to preclude them.

12 MR. MONSOUR: Okay. And I would probably -- let me
13 short-circuit this. I would probably ask him if shrinkage,
14 contracture or degradation is in here, if there is any warning
15 about it, and then move on.

16 MR. ADAMS: I think you can just ask him if it's in
17 there, that's it.

18 MR. MONSOUR: That's what I'm going ask him.

19 THE COURT: If it's in there.

20 MR. MONSOUR: Yes.

21 MR. ADAMS: But not whether --

22 THE COURT: His point is that asking about a warning,
23 if there is a warning in there about it, given his already
24 testimony about shrinkage and degradation, is, at the very
25 least, Mr. Monsour, an implied criticism, so you are free to

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1 ask him if it's in there and nothing further.

2 MR. MONSOUR: Gotcha.

3 (Sidebar concluded.)

4 BY MR. MONSOUR:

5 Q. Now, you had talked before about the four major
6 complications: Degradation, shrinkage, and deformation. Do
7 any of those appear in the directions for use as a potential
8 complication?

9 A. No, they are not.

10 Q. Okay. Now, let's go back to looking at something like
11 this from an implanting surgeon's perspective.

12 If -- and I don't know how to say this. If the product
13 shrunk a little bit, might it be okay for them not to warn
14 about it, versus if it shrinks a lot? Do you understand my
15 question?

16 MR. ADAMS: Objection.

17 THE COURT: The objection is sustained.

18 MR. MONSOUR: Okay.

19 BY MR. MONSOUR:

20 Q. Would a surgeon want to know --

21 MR. MONSOUR: Let me rephrase my question. I'm
22 sorry, Your Honor.

23 BY MR. MONSOUR:

24 Q. Would a surgeon want to know -- or would the surgeon need
25 to know to implant something to keep it tension-free the

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1 amount that a product shrinks?

2 MR. ADAMS: Same objection, Your Honor.

3 THE COURT: That objection, given the phrasing of the
4 question, is overruled.

5 THE WITNESS: The -- the answer to that question is
6 yes.

7 BY MR. MONSOUR:

8 Q. Okay. And tell us why.

9 A. Well, again, this device is meant to stay tension-free
10 through the life of the woman and the device. If it
11 contracts, it's ultimately going to come under tension, and,
12 therefore, it would be important to know that before you
13 implant it.

14 Q. Okay. Let's talk about -- and I kind of want to explain
15 the mechanical process of shrinkage, degradation, with regard
16 to voiding dysfunction in someone like Ms. Blankenship over
17 there. So if we could -- I'd like to kind of talk about it,
18 and I'm going to draw a very crude drawing -- law school, not
19 art school -- crude drawing, that shows here is the urethra
20 cutting this way, looking at the hole, the urine would flow
21 through this way, the tube would be coming out here. The
22 sling would be placed underneath. Okay?

23 A. (Nods head.)

24 Q. If the sling shrinks, what does it do? Can you, I guess,
25 kind of use this chart, if you can see it, and kind of explain

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1 what the shrinking sling would do?

2 A. Well, when the sling shrinks, in this diagram, it would
3 move up and closer to the urethra.

4 Now, in order to impact a woman's ability to empty her
5 bladder efficiently and completely, there are certain things
6 that have to happen. The muscles of the urethra have to
7 relax; the bladder has to contract to accommodate the flow of
8 urine. If there is something underneath the urethra that's
9 not completely obstructing it, it can make it difficult for
10 the urethra then to relax so when the bladder contracts, the
11 bladder empties efficiently and completely. So you don't have
12 to plug up -- it doesn't have to rise up so that the opening
13 of the urethra gets smaller for it to impact the ability of a
14 woman to completely and effectively empty her bladder.

15 Q. So, if I understand, it moves up, it shrinks up this way,
16 but it irritates it?

17 A. That is correct. It doesn't allow it to go through the
18 relaxation process that is necessary for the bladder to
19 effectively or completely empty all the urine.

20 Q. And what happens if it actually pinches the urethra?

21 A. Well, then it will make the woman actually retain urine,
22 what we call urinary retention, which is the worst form of a
23 dysfunction void.

24 Q. Okay. I want to move on to the topic of degradation.

25 And, other than what you've seen when you've actually seen it

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1 degrade and little pieces of it fleck off, other than you
2 seeing something like that, visually, and upon explant, have
3 you actually read literature, is it recognized in the
4 literature that polypropylene degrades when it's put in the
5 body?

6 A. Yes.

7 Q. And what does the literature say?

8 A. Well, from back in the '70s, it was shown that very
9 strong acids and a substance called peroxide can actually
10 start the degradation process. In the '80s --

11 MR. ADAMS: Objection, Your Honor. May we approach?

12 THE COURT: Yes, sir.

13 (The following occurred at sidebar.)

14 MR. ADAMS: Again, this is an area outside his
15 report. You've read his report. He doesn't give opinions
16 about the degradation process. He's not a materials science
17 expert. I wish we could just keep him to his report.

18 MR. MONSOUR: Except for the fact that Judge Goodwin
19 specifically wrote that he could talk about degradation and
20 this is part of the degradation process.

21 MR. ADAMS: He said he could talk about degradation
22 with respect to what he's seen in his practice, not about
23 literature and materials science.

24 MR. MONSOUR: I can pull the literature, the
25 reference to the literature if you would like, Your Honor. It

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1 says literature and his clinical experience.

2 THE COURT: It does. He goes back to a prior ruling
3 that he's made with respect to this doctor in the Ethicon case
4 and he affirms it here, finding that the doctor's qualified to
5 offer the opinion that vaginally implanted polypropylene mesh
6 degrades based on his clinical experience as well as his -- as
7 well as his -- I'm sorry -- and as is in the scientific
8 literature and academic papers. So it's not based simply on
9 his clinical experience.

10 MR. MONSOUR: Correct.

11 THE COURT: And, again, I read this opinion as him
12 adopting and reaffirming his opinion in the Ethicon case.

13 MR. ADAMS: Okay. I guess the problem that I'm
14 having is I don't have that report from Ethicon but I do have
15 his report in this case and he doesn't talk about it.

16 THE COURT: All right.

17 MR. ADAMS: My objection, while Judge Goodwin may
18 have been referring to Ethicon, my objection would be his
19 report in this case doesn't talk about degradation and the
20 process of degradation. He talks about shrinkage and
21 contraction.

22 THE COURT: All right. I overrule the objection
23 based on the Court's ruling. I also find that the Court's
24 ruling was specific such that it should have put all of the
25 parties on notice that he was referring back to his ruling in

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1 Ethicon. And, for that reason, I'm going to permit him to
2 discuss it.

3 MR. MONSOUR: Thank you, Your Honor.

4 MR. ADAMS: Thank you.

5 (Sidebar concluded.)

6 BY MR. MONSOUR:

7 Q. I'm not sure exactly where we were when we parted but
8 let's go back.

9 Does the literature confirm that polypropylene degrades
10 when it's implanted transvaginally and in the human body?

11 A. That is correct.

12 Q. Is the vagina -- Mr. Adams, on opening, got up and talked
13 about how polypropylene had been used in many areas of the
14 body for 50-something years and it helps great.

15 Is the vagina an area of the body that might treat a
16 polypropylene mesh different than the abdomen?

17 A. That is also correct.

18 Q. Explain to the jury why.

19 A. Well, there are three factors inside the vagina that make
20 the use of polypropylene inside the vagina cause concern:

21 Number one, it has a very high concentration of nerves.
22 It has one of the higher concentrations in the body.

23 Number two, it has bacteria. It's virtually
24 impossible to completely remove all the bacteria from the
25 vagina.

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1 And, number three, it produces peroxide. There is a
2 bacteria actually in the vagina that eats the starch made by
3 the cells that line the vagina and creates acids and peroxide.

4 Q. Okay. If someone were to say the abdomen is the same as
5 the vagina, with regard to mesh, that's just not true?

6 A. There isn't the same concentration of nerves in the
7 abdomen. There -- it's much easier to clear an abdominal
8 incision to make it sterile for surgery and clear the
9 bacteria, and the abdomen doesn't produce peroxide.

10 Q. Okay. Peroxide. Is peroxide what's known in the
11 scientific community as a strong oxidizing agent?

12 A. That is correct.

13 Q. Now, in light of the fact that the vagina has -- versus
14 the abdomen, more nerves, more bacteria, and peroxide, do you
15 believe that polypropylene is not well suited for implantation
16 transvaginally to treat stress urinary incontinence in women?

17 A. That is correct. I find it an improper material to be
18 used as a permanent implantation to treat stress urinary
19 incontinence in women.

20 Q. Was it known that polypropylene degraded in -- with
21 slings, that there was degradation of polypropylene in slings,
22 polypropylene slings, implanted transvaginally prior to the
23 Obtryx being launched?

24 A. That is correct.

25 Q. Name me the article.

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1 A. It's a study that came out in 2004 by a doctor named A.C.
2 Wang who followed up 700 patients that had slings. And when
3 they had problems, which is a recurrent erosion, meaning that
4 it eroded through the vagina, and this -- these were difficult
5 to treat, he took the mesh out and looked at it under the
6 microscope and saw fragmentation of the mesh filaments. And
7 his conclusion was that this is not an inert product and that
8 it needs to be looked at, what the long-term implications are,
9 with epidemiologic studies.

10 Q. All right. And that's a great segue to the next thing
11 we're going to talk about, which is studies.

12 Previously in this trial Mr. Adams showed a slide of 22
13 studies that were -- he called them studies that were done on
14 the Obtryx. And he read an editorial that talked about
15 numerous other studies, and he went through that with
16 Dr. Pence. He used that editorial yesterday with Dr. Pence a
17 number of times. The editorial that he talked about was
18 called the AUGS statement. Are you familiar with it?

19 A. Yes.

20 Q. Was the AUGS statement a discussion of the Obtryx Sling
21 specifically?

22 A. No.

23 Q. Okay. Is it fair to say that it was an editorial that
24 was a generalization?

25 A. That is correct.

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1 Q. Written by how many people?

2 A. Five.

3 Q. Five.

4 Mr. Adams showed 22 studies, and this is his slide from
5 opening. I will trust him that these are the only ones. Do
6 you know of any other Obtryx studies?

7 A. No, I do not.

8 Q. Okay. I don't want to go through these in too great a
9 detail, because if the jury is not sick of me yet, they want
10 want to -- they will be very sick of me soon. So I will
11 attempt to narrow my questioning.

12 We went through these 22 last night, right?

13 MR. ADAMS: Objection, Your Honor. May we approach?

14 THE COURT: Yes, sir.

15 (The following occurred at sidebar.)

16 MR. MONSOUR: I'm getting there.

17 MR. ADAMS: I know, but you don't -- yeah, the
18 studies, and I told Mr. Monsour about it, and he told me he
19 would just talk about the two studies, Ross and Cholhan. And
20 now he's trying to talk about all the studies. This expert
21 didn't -- he has a reliance list of material. It only
22 included Ross and Cholhan. He probably shouldn't have shown
23 that slide. Now he's talking about last night we reviewed
24 these studies. I mean, I'm getting bushwhacked here. He
25 didn't even review these studies, a little here at the time of

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1 his deposition. So how can you -- how can you legitimately
2 say this is fair?

3 MR. MONSOUR: I've never had anybody object to me
4 using the slide that they showed in opening before and saying
5 that I shouldn't show it to the jury after he showed it to the
6 jury, point one.

7 Point number two, I'm going to say of these, only
8 five of these were actually published in the journals, full
9 articles that were published in journals, which were the best
10 two. Let's talk about those two. You just interrupted me 90
11 seconds too soon.

12 MR. ADAMS: Well, he doesn't even know -- he didn't
13 know that until last night because he never looked at the
14 studies.

15 THE COURT: It is opinion regarding studies that have
16 not been listed and disclosed and I'm going to exclude it.

17 MR. MONSOUR: Okay.

18 THE COURT: He certainly can testify to those studies
19 on which he based his opinion.

20 MR. MONSOUR: Okay.

21 THE COURT: And any studies that he's made comment on
22 that he's previously disclosed to counsel. But I would agree,
23 not that anyone can bushwhack Mr. Adams, but I would agree
24 with him that those opinions regarding studies that haven't
25 been disclosed are not permitted.

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1 MR. MONSOUR: Okay, okay.

2 THE COURT: I preserve the defendant's -- the
3 plaintiffs' objection and exception.

4 MR. ADAMS: I understand you're going to move on to
5 Cholhan and Ross, correct?

6 MR. MONSOUR: Yeah.

7 THE COURT: Okay.

8 MR. ADAMS: Okay. So take the slide down and we
9 don't have to do anything more about his critique on our
10 studies which was undisclosed. Is that fair?

11 MR. MONSOUR: Taking my slide down that you think is
12 unfair --

13 MR. ADAMS: That's fine.

14 (Sidebar concluded.)

15 BY MR. MONSOUR:

16 Q. Would you -- take that down. Thank you.

17 On that list of studies, I want to focus on two of the
18 studies.

19 There were -- on the list, there's only one randomized
20 controlled trial; is that a fair statement?

21 A. That is correct.

22 Q. Well, maybe. Or, well, maybe Tracan is, but we won't
23 talk about that one.

24 I want to talk about the Ross study first. I don't
25 want to talk about the other ones. But I want you to tell the

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1 jury, first, I want to start off with the Ross study, and if
2 we could pull it up.

3 The Ross study is what's called a randomized controlled
4 trial. Correct?

5 A. That is correct.

6 Q. And tell the jury why a randomized controlled trial is
7 what's called -- do they call it Level 1 evidence?

8 A. That is also correct.

9 Q. Why? Why is that the best type of evidence that someone
10 can use to evaluate a product? Randomized controlled trial,
11 Level 1. Why is that the most important type?

12 A. Well, first of all, during the randomization process,
13 where no one but a random selected computer-generated list
14 decides what treatment the patient gets, so it eliminates
15 bias. It makes sure that both groups are as similar to each
16 other as possible, so that it eliminates the patient factor.
17 It is determined ahead of time what number of patients you
18 need to have to prove the end point, and you look at things
19 going forward instead of looking at things going backward
20 through the retrospectoscope.

21 Q. Okay. A friend of mine explained to me one time, he said
22 if you don't randomize it and you were checking for people's
23 ability to run a mile and you put the smokers all in one group
24 and the people that jogged every morning in another, you'd get
25 varying results. Is that fair?

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1 A. That -- that is correct.

2 Q. That's why you mix them up and send them into two
3 different groups and you randomize it, right?

4 A. That is correct.

5 Q. All right. Now, this Ross study, is it authoritative?

6 A. That is correct.

7 Q. Is it published in a reputable journal?

8 A. That is correct.

9 Q. Have you actually been a peer reviewer for this journal?

10 A. That is correct.

11 Q. And the article is the American College of Obstetrics and
12 Gynecologists?

13 A. The journal is actually called *Obstetrics and Gynecology*.

14 Q. *Obstetrics and Gynecology*, I'm sorry.

15 MR. MONSOUR: Your Honor, at this point in time I
16 would like to offer plaintiffs' Exhibit 444, also known as the
17 Ross study.

18 MR. ADAMS: Your Honor, no objection for use as a
19 learned treatise but I don't think it comes into evidence.

20 THE COURT: Is that your intended use, counsel, or
21 are you offering its admission?

22 MR. MONSOUR: I am -- I just want to use it for a
23 demonstrative with the jury at this point in time.

24 THE COURT: All right. Go ahead, please.

25 MR. MONSOUR: And I can show it to the jury?

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1 THE COURT: Yes, sir.

2 MR. MONSOUR: Thank you.

3 MR. ADAMS: No objection to that Your Honor.

4 (PLAINTIFFS' EXHIBIT 444 WAS MARKED FOR IDENTIFICATION.)

5 MR. MONSOUR: Okay. If we can pull up, Evan, the
6 Ross study.

7 (The document was published to the jury.)

8 BY MR. MONSOUR:

9 Q. Now, the first thing I want to do is let's look at the
10 top and it says -- it says, "Transobturator Tape Compared With
11 Tension-Free Vaginal Tape For Stress Incontinence, a
12 Randomized Controlled Trial." Correct?

13 A. That is correct.

14 Q. Now, the first author is Dr. Sue Ross. That's why we
15 call it the Ross study. Correct?

16 A. That is correct.

17 Q. Now, it's comparing the transobturator tape versus the
18 tension-free vaginal tape. So what two products is it
19 comparing?

20 A. It's comparing the Obtryx with another sling that we
21 talked about earlier that goes behind the pubic bone.

22 Q. Okay. And, if you remember, it's comparing the one that
23 goes more this way to the one that goes more up and down.
24 Correct?

25 A. That is correct.

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1 Q. All right. So if we can go down, and let's look down at
2 the bottom, in the -- right here, it says financial
3 disclosure, and it says, "Dr. Ross and Robert accepted
4 grant-in-aid research funding from Boston Scientific." Do we
5 see that?

6 A. Yes.

7 Q. Now, if you go up about three paragraphs in the small
8 italicized print, you see right there, in the second one:
9 Peer-Reviewed funding was received from Alberta Heritage Fund
10 for medical grant. Grant-in-Aid industry funding was received
11 from Boston Scientific. Do we see that?

12 A. Yes.

13 Q. And then if we go down to the very bottom of the page, on
14 the left-hand side, you see a date. And it's a little below
15 that. There you go. You see a date from December, 2009,
16 right?

17 A. That is correct.

18 Q. Okay. And if we go to the next column at the bottom,
19 before we get into the subject matter, it talks about how it
20 is the type of evidence, Level 1 evidence. All right.

21 You believe this is a reliable study?

22 A. That is correct.

23 Q. Tell us why.

24 A. Well, first, it is a prospective randomized controlled
25 trial. It has a study methodology which is reliable. It has

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1 a large cohort -- or number of patients in it, 199 patients.
2 They did a statistical analysis ahead of time, which is called
3 a power analysis, and that analyzes the number of patients
4 that you need in the study to be able to show that there is a
5 difference between the two groups and that difference between
6 the two groups is due to different treatment modalities.

7 Q. Okay. If you would go to the next page, to the
8 highlighted area. And it says, just so we know, to clarify,
9 it says, "Boston Scientific devices were used for all
10 procedures: The outside-in Obtryx Halo mid-urethral sling
11 system was used for transobturator tape procedures." Do you
12 see that?

13 A. Yes.

14 Q. All right. Is that was what was used, the Obtryx that
15 was used in Ms. Blankenship?

16 A. That is correct.

17 Q. Okay. And I have not looked at which trocar was used in
18 case I get that wrong, but it was the Obtryx procedure?

19 A. That is correct.

20 Q. All right. Now, if we go to the next area that I have,
21 Evan, on Page 1290 at the bottom of the left column and the
22 top of the right-hand column.

23 When discussing the Obtryx, it says -- can you read
24 this for us?

25 A. However, on vaginal examination, the tape was palpable

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1 for 68 women, or 80 percent, in the transobturator group, and
2 24 women, or 26.7 percent, in the TVT group.

3 Q. Okay. Oh, keep going.

4 A. More women in the transobturator tape group experienced
5 groin pain during vaginal palpation, which came to a 15.3
6 percent in the transobturator group, and 5, or 5.6 percent, in
7 the TVT group.

8 Q. This was the first randomized controlled trial ever done
9 by Boston Scientific on the Obtryx, correct?

10 A. That is correct.

11 Q. And it notes palpable mesh in 80 percent of the women
12 that got Obtryx.

13 A. That is correct.

14 Q. What does "palpable mesh" mean?

15 A. Well, it means that you could feel it different from what
16 you would expect along the front wall of the vagina underneath
17 the urethra. If there was normal tissue integration, it
18 should not be able to be felt.

19 Q. Okay. If you would go to the next page, the highlighted
20 area. Would you read this for me?

21 A. Despite the lack of differences in cure rates between
22 the two groups, it was found on digital vaginal examination
23 that more women in the transobturator tape group had tape that
24 was palpable and experienced groin pain compared to the women
25 in the TVT group.

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1 Q. What does that mean?

2 A. Well, that means when they pushed on the tape, it hurt
3 them in their groin.

4 Q. Go to Page 1293. Would you read what the article says
5 here.

6 A. "In these circumstances, where there is the potential for
7 long-term adverse effects of a procedure, we believe that
8 benefit should be demonstrated before adopting a newer
9 procedure into clinical practice."

10 Q. In Boston Scientific's own study, they're saying that
11 they should have determined that this was safe before they put
12 it on the market?

13 MR. ADAMS: Objection, Your Honor, that's leading and
14 it's a mischaracterization.

15 MR. MONSOUR: You tell me what it says.

16 THE COURT: The objection to the question is
17 sustained, counsel.

18 Doctor, you can answer the subsequent question.

19 THE WITNESS: Well, what they say is that you should
20 show that the benefit outweighs the risk before new procedures
21 are placed on the marketplace.

22 BY MR. MONSOUR:

23 Q. And this is in the face of examining the Obtryx data?

24 A. That is correct.

25 Q. In Boston's study, randomized controlled trial, done five

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1 years after the product was released on the market?

2 A. That is also correct.

3 Q. Go down to the next. And then onto the next page, if you
4 could or -- okay. We will read this. It follows on two
5 pages, Doctor, if you will read this.

6 A. "The presence of palpable tape is concerning; longer-term
7 follow-up is needed to determine whether this outcome leads to
8 extrusion or resolves over time."

9 Q. Keep reading.

10 A. "Until long-term follow up is available from this and
11 other trials, TVT should remain the mid-urethral sling
12 procedure of choice."

13 Q. So what the article says, the Boston Scientific
14 randomized controlled trial done five years too late, it says,
15 do this procedure; don't do this procedure. (Indicating.) Am
16 I summarizing that fairly for the jury?

17 A. That is correct.

18 Q. Ms. Blankenship, the following year, had this procedure,
19 didn't she? (Indicating.)

20 A. She actually had her procedure in April of 2009.

21 Q. That same year.

22 A. That is correct.

23 Q. I'm sorry. I got my dates wrong.

24 In your opinion, is this a good study for BSC?

25 MR. ADAMS: Objection, Your Honor. Vague and

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1 ambiguous.

2 MR. MONSOUR: Let me reask my question.

3 BY MR. MONSOUR:

4 Q. Is this study an endorsement of the Obtryx?

5 MR. ADAMS: Same objection, Your Honor.

6 THE COURT: The objection to this question being
7 vague and ambiguous is overruled, counsel.

8 MR. ADAMS: Also, Your Honor, I will object on
9 foundational grounds, too.

10 THE COURT: Again, he has indicated that he has
11 reviewed this study. I'm going to overrule the objection and
12 permit the doctor to answer the last question, if he can.

13 THE WITNESS: This would not be an endorsement.

14 BY MR. MONSOUR:

15 Q. Let's go to the Cholhan study. I'm sorry. Would you
16 take it down?

17 MR. MONSOUR: I'm sorry, Your Honor. Let me lay the
18 foundation for it.

19 BY MR. MONSOUR:

20 Q. Are you familiar with the Cholhan study?

21 A. That is correct.

22 Q. And it was published in what journal?

23 A. *The American Journal of Obstetrics and Gynecology.*

24 Q. Is that an authoritative journal?

25 A. That is correct.

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1 Q. Have you served -- these two articles were published in
2 two respected journals; is that a fair statement?

3 A. That is correct.

4 Q. Are you a reviewer for them? Or have you been?

5 A. Yes, I have been.

6 Q. And, as a reviewer, what does that mean?

7 A. When I get an article to review for publication, my job
8 is to go through the study to look at the methodology, the
9 statistics used, to look at the conclusions that are drawn, to
10 see if this is a paper that is worthy of publication, that
11 will add something to the scientific literature.

12 MR. MONSOUR: Okay. At this point in time, Your
13 Honor, I would offer Exhibit 270, the Cholhan study, to --

14 THE COURT: As a learned treatise, counsel?

15 MR. MONSOUR: Yes, Your Honor.

16 MR. ADAMS: No objection to that as a learned
17 treatise.

18 THE COURT: All right.

19 MR. MONSOUR: The same as before, just to show it to
20 the jury.

21 THE COURT: Yes, sir.

22 MR. MONSOUR: Can I go ahead and put it up?

23 THE COURT: Yes, sir.

24 MR. MONSOUR: Thank you.

25 (PLAINTIFFS EXHIBIT 270 WAS MARKED FOR IDENTIFICATION.)

—Rosenzweig - Direct - Monsour—

1 (The document was published to the jury.)

2 MR. MONSOUR: Do you have a copy?

3 THE WITNESS: I have what is being shown up on the
4 screen.

5 MR. MONSOUR: I'll give you a copy just in case.

6 Your Honor, would you like a copy?

7 THE COURT: Thank you.

8 THE WITNESS: Thank you, sir.

9 BY MR. MONSOUR:

10 Q. Now, the Cholhan study says -- it's titled "Dyspareunia
11 Associated With Paraurethral Banding in the Transobturator
12 Sling." Is that correct?

13 A. That is correct.

14 Q. What is dyspareunia?

15 A. Pain with sexual intercourse.

16 Q. Okay. What is paraurethral banding?

17 A. Feeling bands on each side of the urethra.

18 Q. Okay. Why am I not supposed to feel bands on either side
19 of the urethra?

20 A. Well, the intention of the product is to integrate into
21 the tissue so that you don't feel anything along the front
22 wall of the vagina because if you do feel something, that can
23 then lead to discomfort for either the man or the woman during
24 sexual intercourse.

25 Q. Okay. You talked before about shrinkage, contraction,

—Rosenzweig - Direct - Monsour—

1 and degradation. Is banding associated with those?

2 A. That is correct.

3 Q. Okay. So explain how in the vagina banding would take
4 place.

5 A. Well, when you take a tape that is about 1.1 centimeter
6 wide and it contracts, it's going to get narrower, and that
7 can be felt as a band. When it contracts, it creates more
8 tension and that can be felt as a firm area or a band.

9 Q. Okay. The author's name is Dr. Hilary Cholhan. It's
10 actually a he, Hilary, correct?

11 A. That is correct.

12 Q. Okay. And Dr. Cholhan, if you will look down below the
13 page in the left column, it notes that the study is from 2009,
14 and it notes that Dr. Cholhan is a paid consultant and
15 instructor for Boston Scientific, correct?

16 A. That is correct.

17 Q. Okay. Now, if we go up to the top of the page in the
18 summary of the article, under the conclusion, would you read
19 what the conclusion is?

20 A. "We have identified paraurethral banding as a previously
21 unreported complication of the transobturator sling. Surgeons
22 should be aware of the paraurethral banding and subsequent
23 internal dyspareunia as a potential complication."

24 Q. As a surgeon, if a product caused banding as a result of
25 shrinkage and contraction, is that something that you would

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1 want to know?

2 A. That is correct.

3 Q. Why would you want to know that in treating patients for
4 these problems?

5 A. Well, number one, if it was associated with symptoms, and
6 symptoms like dyspareunia, where a woman would have pain
7 during intercourse, I would want the patient to know about
8 that, that that was a possibility, to determine if this
9 product was an appropriate product for her.

10 MR. MONSOUR: If you will go two pages over. And I'm
11 sorry. Evan, if you will go back to the second page, I want
12 to orient the jury, in the middle of the first column on the
13 left, go down about halfway down the page and you'll note
14 where it mentions Obtryx.

15 BY MR. MONSOUR:

16 Q. The product that was used in this study was what
17 transobturator tape?

18 A. The Obtryx tape.

19 Q. The same tape that was put in Ms. Blankenship, Ms. Tyree,
20 Ms. Wilson, and Ms. Campbell?

21 A. That is correct.

22 Q. All right. Now, if we can then go back to the third
23 page, 481, middle column, middle of the middle column, would
24 you read what that states?

25 A. "Although our study is limited by relatively small

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1 numbers, we believe a 24 percent postoperative dyspareunia
2 rate is concerning."

3 Q. Okay. If we can go to the next column, Evan.

4 Would you read from there?

5 A. This situation may be avoidable, since the transobturator
6 sling arms traverse beneath the mid-urethra directly lateral
7 -- excuse me -- directly laterally toward the medial notch of
8 the obturator foramen.

9 Q. I think you misread that. I think it said the situation
10 may be "unavoidable."

11 A. Oh, I thought I said "unavoidable." I'm sorry if it came
12 out "avoidable."

13 Q. Is an unavoidable consequence of paraurethral banding,
14 which leads to 24 percent of the women having postoperative
15 painful intercourse, is that the type of information that you,
16 as a surgeon, would want to know if you were going to consider
17 implanting this product?

18 A. That is correct.

19 Q. And let's go to the conclusion on the last page, and
20 let's see if Dr. Cholhan agrees with you.

21 A. It is important for the surgeons who perform the
22 transobturator slings to be aware of paraurethral banding and
23 the internal dyspareunia as a potential complication of this
24 procedure.

25 Q. So you are in agreement with Dr. Cholhan who is a paid

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1 consultant and instructor for Boston Scientific?

2 A. That is correct.

3 Q. Now, I want to focus on Ms. Blankenship.

4 She had what condition that necessitated her having the
5 sling implanted?

6 A. Stress urinary incontinence.

7 Q. And it was implanted -- I've got my date here in my
8 handy-dandy notes -- in April of 2009?

9 A. That is correct.

10 Q. Okay. I got it wrong before.

11 If I look through her medical records, she has, I guess
12 the first symptom noted with the sling in January of 2011,
13 about 21 months later. Is that correct?

14 A. That is also correct.

15 Q. Now, you had mentioned before long-term studies,
16 randomized controlled trials and the need for long-term
17 studies. I've seen several studies on these products. Many
18 of them are 12-month studies. Do you consider a 12-month
19 study to be a long-term study?

20 A. No, that would be a short-term study.

21 Q. Okay. If a study goes out in time --

22 MR. ADAMS: (Indicating.)

23 THE COURT: Yes, sir.

24 BY MR. MONSOUR:

25 Q. If a study goes out in time long-term and it only looks

—Rosenzweig - Direct - Monsour—

1 at data at one year, that's the only data that it can collect,
2 what's gone from day zero to one year, correct?

3 A. That is correct.

4 Q. In looking at a permanent implant like the Obtryx Sling,
5 why would you want data that's collected more than one year
6 after implant?

7 A. Well, obviously, if you only look at one year, you will
8 only be able to determine what consequences there are of that
9 procedure that will happen in one year.

10 Q. Okay. Jeanie Blankenship's problems, the first I could
11 find, and I'm sure I'll be corrected if I'm wrong, happened at
12 about 21 months, the first symptom. And I'll write "JB" on
13 there.

14 Can you use Jeanie Blankenship and give an example as
15 to why she is a perfect example why one-year data is
16 inappropriate for a permanent implant?

17 A. Well, at one year, she would have been considered a
18 treatment success, that the procedure was efficacious or
19 effective, and that she did not have any complications.

20 Q. So if we looked at one-year data with Jeanie Blankenship,
21 Boston Scientific and her doctor would say she's a screaming
22 success; fair statement?

23 A. That is correct.

24 Q. All right. Now, she notes that she has voiding
25 dysfunction in -- I guess it shows up about a year after her

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1 first -- or it shows up again about a year after she has her
2 first problems in February of 2012, and it's confirmed by
3 urodynamic studies; is that correct?

4 A. That is correct.

5 Q. So what does her doctor do to try and help her out?

6 A. He takes her to the operating room and does a procedure
7 to attempt to release or cut the sling to relieve her voiding
8 dysfunction.

9 MR. MONSOUR: If you would put up the surgery slide.

10 Your Honor, I'm sorry. I would like to offer the --
11 I would like to offer at this point in time, Your Honor, Joint
12 Exhibit Number 18, specifically, Pages 121 and 122.

13 MR. ADAMS: No objection. It's already been offered
14 by us this morning.

15 MR. MONSOUR: Oh, all right. And if you would pull
16 this up.

17 BY MR. MONSOUR:

18 Q. If we look on this surgery report, the doctor is talking
19 about the surgery, and he says -- can you read this for us,
20 starting with scarring?

21 A. It says, scarring in the periurethral area both left and
22 right were more prominent on the patient's right side. I
23 could not definitively identify the transobturator tape
24 despite careful dissection and extensive dissection all the
25 way to the proximal urethra.

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1 Q. Okay. What does that tell you as a surgeon that operates
2 in the pelvic floor?

3 A. That there was a significant amount of scarring that took
4 place around the obturator sling.

5 Q. Is that problematic for a patient?

6 A. That is correct.

7 Q. Why?

8 A. Well, we saw it in the last two studies that we looked
9 at. This kind of scarring can lead to pain; can lead to groin
10 pain, if it's pushed on; can lead to pain with intercourse.
11 This kind of scarring can also lead to a voiding dysfunction,
12 where the patient might have difficulty effectively emptying
13 her bladder.

14 Q. Okay. Does that go back to this drawing that I have done
15 before, where it shows the voiding dysfunction and the sling
16 and the contraction?

17 A. That is correct.

18 Q. Okay. So, if we keep reading, it notes, would you
19 keep -- would you continue there under "several areas"?

20 A. "Several areas of scarring with possible mesh was excised
21 and submitted for pathologic examination."

22 Q. And then down here, if you would.

23 A. "Estimated blood loss was between 700 and 800
24 milliliters."

25 Q. Okay. Let's talk about that. Why does that stand out to

—Rosenzweig - Direct - Monsour—

1 you?

2 A. That is a significant blood loss. We would call that
3 gynecologic surgical hemorrhage.

4 Q. Would that be an indicator that this was a very difficult
5 surgery?

6 A. That is correct.

7 Q. Okay. Give me a perspective as to how much blood loss
8 700 to 800 milliliters is, approximate percentage of the blood
9 that's in the body, how much of it was lost during this
10 surgery to cut out a portion of her mesh?

11 A. The average volume of blood in an average human being is
12 about 5 liters. This was 20 percent or one-fifth of their
13 blood volume -- of her blood volume.

14 Q. Is that a lot to you?

15 A. That is significant, yes.

16 Q. Okay. Now, did this surgery fix Ms. Blankenship and cure
17 her of all the problems that she had?

18 A. She did not complain of difficulty effectively emptying
19 her bladder after this procedure. She continued, however, to
20 have discomfort and pain.

21 Q. Okay. Now, if I understand it correctly, the surgeon cut
22 out some of the mesh during this procedure; is that right?

23 A. That is correct.

24 Q. So could I safely say something like there and there was
25 cut out? (Indicating.) Or do we know?

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1 A. I don't think we know. I would say that it was probably
2 less than that.

3 Q. Okay. So maybe it was just cut? (Indicating.)

4 A. That is correct.

5 Q. All right. So, now, after the surgery, if just a little
6 area is cut, what remains of all of this mesh that is left
7 inside of Mrs. Blankenship? (Indicating.) What's going on
8 with this mesh, over here, that's still in her?

9 A. Well, the same process that was going on before, the
10 degradation, the contraction, the chronic foreign body
11 reaction, chronic inflammation, and deformation are going to
12 continue to take place.

13 Q. Now, she continues to have problems to this day?

14 A. That is correct.

15 Q. From the Obtryx mesh that was left behind in her.

16 A. That -- excuse me.

17 Q. Correct?

18 A. That is correct.

19 Q. And the nature of her problems are what?

20 A. Well, she currently has what's called levator spasm or
21 pelvic floor muscle spasm. And, in fact, it has gone from a
22 reaction to something that is actually placed inside the
23 vagina to an anticipation of pain with just the anticipation
24 of something that is being placed inside the vagina. This is
25 what we would characterize as more of a centralization of the

—Rosenzweig - Direct - Monsour—

1 pain, where you don't actually need the peripheral response to
2 pain before the patient actually starts reacting to the pain.

3 Q. So as something approaches, it goes off?

4 A. That is correct.

5 Q. How do you know that it's the mesh that's causing these
6 problems that you described? How do you know it's not
7 something else in her past?

8 A. Well, number one, the mesh is going through the muscle.
9 It's still in the muscle of the transobturator internus
10 muscle. The obturator internus muscle is connected with the
11 pelvic floor muscles that were noted to be spasming on the
12 independent medical evaluation that was done, that noted this
13 pelvic floor muscle spasm and anticipate -- anticipatory
14 pelvic floor muscle spasm.

15 After reviewing her medical records, I did not see
16 anything that would lead to irritation of the muscle that
17 would lead to pelvic floor muscle spasm except mesh, a foreign
18 body, in the muscles of the pelvic floor.

19 Q. And that would be through the obturator approach?

20 A. That is correct.

21 Q. Let's rule out another -- some other potential causes
22 that I think Boston Scientific might bring up, might try to
23 point the finger somewhere else, so let's talk about them.

24 From your view of the medical records, did Dr. Lassere
25 just put the sling in too tight?

—Rosenzweig - Direct - Monsour—

1 A. No, he did not.

2 Q. How do you know?

3 A. Looking at the operative report, he used an instrument
4 between the tape and the urethra, like we saw on the video, to
5 assure that tape was not placed too tight.

6 Q. Okay. And if we go and we look at this document, we
7 talked about shrinkage, the concept of shrinkage in the body,
8 of the mesh. Is that a concept that happens immediately or
9 does it take place over time?

10 A. Well, it usually takes place over time.

11 Q. Okay. So if the first symptoms that we see of voiding
12 dysfunction are approximately two years after implantation,
13 does that tell you it's not surgeon error but is instead
14 device error?

15 A. If it was due to the surgeon placing it too tight, her
16 symptoms would have appeared in the normal post-operative
17 period instead of almost two years later.

18 Q. Okay. I'm going to run through a few others that I
19 believe their expert is going to blame.

20 MR. ADAMS: Objection, Your Honor, to the
21 mischaracterization.

22 THE COURT: The objection to that characterization is
23 sustained.

24 MR. MONSOUR: Okay.

25 BY MR. MONSOUR:

—Rosenzweig - Direct - Monsour—

1 Q. Let me ask it this way: Do you believe that preexisting
2 endometriosis causes the problems that you state are coming
3 from the Obtryx Sling?

4 A. No.

5 Q. How can you rule that endometriosis out?

6 A. Well, endometriosis usually does not cause muscle spasm
7 unless the endometriosis is in the muscle. So she wasn't
8 complaining of pain and pelvic floor muscle spasm before her
9 sling, and she's also had a procedure to block her tubes.
10 Then I ruled out endometriosis as a cause of her symptoms
11 because the most common way endometriosis happens, and what
12 endometriosis is is when the normal lining of the womb that is
13 shed every month during the menstrual period, and normally
14 comes out through the cervix and the vagina, goes out through
15 the tubes and implants inside the abdomen. So it's -- the
16 most prevalent theory is what we call retrograde menstruation.
17 At a young age, she had her tubes tied, and she never got
18 pregnant, which means that those tubes are blocked and if
19 they're going to block the -- the egg and the sperm from
20 getting together to create a pregnancy, more likely than not,
21 it would also prevent the flow of blood out.

22 Q. Can you rule out pelvic inflammatory disease as a cause
23 of her chronic pain and dyspareunia?

24 A. Yes.

25 Q. How?

—Rosenzweig - Direct - Monsour—

1 A. Well, pelvic inflammatory disease is an infection caused
2 by bacteria that start at the cervix, move their way through
3 the uterus, and then ends up in the tube. And her tubes are
4 blocked.

5 Also, her pelvic inflammatory disease was treated, and
6 the vast majority of women who had an episode of pelvic
7 inflammatory disease and are treated don't end up with what's
8 called chronic pelvic inflammatory disease, where they have an
9 invalid infection inside their tubes.

10 Q. How do the urinary tract infections that were mentioned
11 on opening play into this?

12 A. Well, in -- one of the records from her prior
13 practitioner, that prior practitioner opined that her urinary
14 tract infections are due to sexual intercourse, what is
15 commonly known as honeymoon cystitis, where the active
16 intercourse actually pushes bacteria from the vagina and the
17 far end of the urethra, where the urine comes out, into the
18 bladder, and actually treated her with an antibiotic that she
19 would take after the active intercourse to decrease her
20 urinary tract infections.

21 Now, her urinary tract infections cause pain and could
22 cause pain with intercourse, but they cause pain and pain with
23 intercourse while the infection is going on. Once the
24 infection is treated, there isn't pain.

25 Q. Okay. So it's not a permanent problem?

—Rosenzweig - Direct - Monsour—

1 A. That is correct. It is an episodic problem that will
2 resolve with treatment.

3 Q. Okay. There are some prior conization surgeries and
4 surgery that resulted from them. Is that playing a role in
5 the problems that she's having with the Obtryx Sling?

6 A. She had abnormal Pap smears in the past, and she had a
7 treatment where a portion of the cervix was removed and cut
8 off, and then the cervix healed. Now, if there is going to be
9 scarring, the scarring is going to be where the surgery was,
10 which is at the cervix. The cervix -- the average length of
11 the vagina is about eight to ten centimeters. The sling is
12 placed within the first one to two centimeters inside the
13 vagina, so we can see that there is a large degree of
14 separation between where the obturator sling is and where her
15 conizations were.

16 Q. Okay. The site of the sling, do you believe that where
17 there was a revision surgery, that the nature of that revision
18 surgery led to additional scarring which was problematic for
19 Ms. Blankenship?

20 A. Well, one of her subsequent treating doctors noted that
21 there was lateral scarring in the vagina, and that lateral
22 scarring was not noted before, and so this is probably a
23 continuation of the contraction, the degradation, and the
24 chronic foreign body reaction that we discussed earlier.

25 Q. Okay. Let's talk about the future for Jeanie. What does

—Rosenzweig - Direct - Monsour—

1 she have to look forward to with regard to taking care of the
2 Obtryx mesh that is still remaining in her that is still
3 causing her problems?

4 MR. ADAMS: Objection, Your Honor. May we approach?

5 THE COURT: Yes, sir.

6 (The following occurred at sidebar.)

7 MR. ADAMS: This is another undisclosed opinion.
8 You've read his report. He doesn't talk about future care and
9 treatment of Ms. Blankenship.

10 THE COURT: All right.

11 MR. MONSOUR: It talks about that she has a permanent
12 problem so it's -- and I believe they asked him about it in
13 his deposition.

14 MR. ADAMS: He's already testified that she has a
15 permanent problem, but for him now to go into what she's going
16 to have to deal with in the future, additional surgeries,
17 things like that, is unfair. That's what he was now
18 disclosing.

19 THE COURT: What did the deposition involve?

20 MR. ADAMS: He did say it was permanent. He said the
21 problems were permanent.

22 THE COURT: He said that here. Were the treatment
23 options for the future gone into?

24 MR. ADAMS: Not future surgeries, no.

25 MR. MONSOUR: I was going to say when we disclosed

—Rosenzweig - Direct - Monsour—

1 that, he said she's going to have a permanent problem, they
2 should have asked, and permanent problem necessarily involves
3 future medical care.

4 THE COURT: All right. Counsel, I'm going to
5 preclude the opinions. If it's not in his report and has not
6 been gone over in his deposition, I don't think it's
7 appropriate for him to give undisclosed opinions during trial.

8 MR. MONSOUR: Okay. Let me go --

9 THE COURT: I preserve any objection and exception
10 for the plaintiffs. Thank you.

11 (Sidebar concluded.)

12 THE COURT: Give me a good stopping place,
13 Mr. Monsour.

14 MR. MONSOUR: How about right now?

15 THE COURT: All right. Thank you.

16 Ladies and gentlemen, I'm going to give you a recess
17 for your lunch. While you're out, do not discuss this case
18 among yourselves or permit anyone to discuss it with you or in
19 your presence, and be in your jury lounge at 1:30 this
20 afternoon. We'll start then.

21 COURT SERVICES OFFICER: All rise. This Court is in
22 recess.

23 (A luncheon recess was taken from 12:06 p.m. to 1:26
24 p.m.)

25 (The Jury returned to the courtroom at

—Rosenzweig - Direct - Monsour—

1 1:26 p.m.)

2 THE COURT: Good afternoon, you all.

3 Mr. Monsour.

4 MR. MONSOUR: Thank you, Your Honor.

5 BY MR. MONSOUR:

6 Q. Are you ready, Dr. Rosenzweig?

7 A. Yes, sir.

8 Q. Okay. When we stopped for lunch we were talking about
9 the permanent nature of Jeanie Blankenship's problems if you
10 remember that.

11 A. Yes, sir.

12 Q. Okay. Does, does Ms. Blankenship still have mesh
13 implanted in her body from the Obtryx even after her revision
14 surgery?

15 A. That is correct.

16 Q. Will this obturator-placed mesh continue to give her
17 problems permanently?

18 A. With a reasonable degree of medical certainty, yes.

19 Q. Will it resolve on its own?

20 A. No.

21 Q. You talked about shrinkage. You talked about
22 contraction. You talked about degradation and flaking. Will
23 that persist as long as the mesh is implanted in Ms.
24 Blankenship?

25 A. More likely than not, yes.

—Rosenzweig - Direct - Monsour—

1 Q. Is it true of all women that have the Obtryx mesh still
2 in their bodies?

3 A. That is correct.

4 Q. Is the transobturator approach with a polypropylene mesh
5 implanted through the transobturator, is that a bad idea?

6 A. In my opinion, yes.

7 Q. Is mesh a safe material to be implanted transvaginally in
8 a woman's vagina?

9 A. No.

10 Q. Are there other treatment options available for women
11 that have far, fewer long-term complications?

12 A. That is correct.

13 Q. This instruction manual, does it warn about shrinkage?

14 MR. ADAMS: Objection, Your Honor.

15 THE COURT: The objection is sustained. We visited
16 this several times. Let's move on.

17 MR. MONSOUR: Okay.

18 BY MR. MONSOUR:

19 Q. Does the literature show valid, long-term proof
20 that the Obtryx is safe?

21 A. No.

22 Q. To confirm that there is still sling material inside Ms.
23 Blankenship, did you ever look at some pathology?

24 MR. ADAMS: Objection, Your Honor. I guess we need
25 to approach.

—Rosenzweig - Direct - Monsour—

1 MR. MONSOUR: This --

2 THE COURT: Come up.

3 (The following occurred at sidebar.)

4 MR. ADAMS: Well, --

5 MR. MONSOUR: It's in his report.

6 THE COURT: Let me hear what the objection is.

7 MR. ADAMS: Yes. My objection is it's outside the
8 scope. I don't believe he did disclose this in the report.

9 MR. MONSOUR: Can I go get the report?

10 MR. ADAMS: I'll get mine too.

11 THE COURT: I have it here somewhere. I thought I
12 did.

13 MR. ADAMS: I'll grab it.

14 MR. MONSOUR: It's either in the report or in the
15 *Daubert* order. I believe it's in the report, Your Honor.

16 THE COURT: Mr. Monsour, repeat your question for me.

17 MR. MONSOUR: "Did you look at any pathology?"

18 THE COURT: Uh-huh.

19 MR. MONSOUR: And if you look on Page 6 of the
20 report --

21 THE COURT: Yes, sir.

22 MR. MONSOUR: -- Dr. Trepeta's examination found
23 sling material, this right here. It's disclosed.

24 MR. ADAMS: This witness observed that Trepeta --
25 Trepeta is going to testify. He didn't make any comments on

—Rosenzweig - Direct - Monsour—

1 the fact that Trepeta did an examination of the pathology.
2 And this witness did not do an examination of the pathology.
3 That was my point.

4 THE COURT: Don't interrupt each other and let me
5 read, please.

6 MR. ADAMS: Certainly, Your Honor.

7 THE COURT: All right. What else? Anything further
8 from either of you?

9 MR. MONSOUR: Mine is only that it's disclosed and
10 that's what I'm asking him about.

11 THE COURT: He has disclosed, based on my review of
12 what you pointed to me on Page 6, that he has apparently
13 reviewed Dr. Trepeta's records, including the fact that he
14 noted pathology. He can testify to that. That's, that is, in
15 fact, disclosed.

16 MR. MONSOUR: Okay.

17 THE COURT: Your question may seem to indicate that
18 he himself observed some type of pathology. You may want to
19 make sure that your question conforms to the opinion that he
20 does discuss having reviewed Trepeta.

21 MR. ADAMS: Your Honor, my additional point is, and I
22 think I know Mr. Monsour well enough that now he's going to
23 try to invoke opinions from this witness about whatever
24 Trepeta observed in the pathology. That's -- he doesn't give
25 any opinions about it. He makes the observation that Trepeta

—Rosenzweig - Direct - Monsour—

1 did an examination. So, that's the only thing he can testify
2 about.

3 THE COURT: I will exclude any opinions. It would
4 seem to me, based on my review of this, that that's one in a
5 number of things that this doctor reviewed in order to
6 formulate his opinions. He's certainly able to testify to
7 that fact.

8 But, of course, he can't testify to Dr. Trepeta's
9 opinions, but he can testify to what he reviewed, including
10 the fact that Trepeta had viewed pathology which is in support
11 of the opinions that he gives in this report.

12 MR. MONSOUR: Thank you.

13 THE COURT: I preserve an objection and exception for
14 the plaintiff to my ruling.

15 MR. MONSOUR: Thank you.

16 (Sidebar concluded.)

17 BY MR. MONSOUR:

18 Q. Dr. Rosenzweig, did you review some pathology
19 slides that were completed by Dr. Trepeta?

20 A. I reviewed Dr. Trepeta's report. I did not review the
21 slides themselves.

22 Q. Did his report confirm the presence of mesh in what was
23 removed from Jeanie Blankenship?

24 A. Yes, it did.

25 MR. MONSOUR: I will pass the witness. No further

—Rosenzweig - Cross - Monsour—

1 questions.

2 THE COURT: Cross-examination, counsel?

3 MR. ADAMS: Thank you, Your Honor.

4 (CROSS EXAMINATION OF BRUCE ROSENZWEIG BY MR. ADAMS)

5 Q. Hi, Doctor. It's Rosenzweig; correct?

6 A. Rosenzweig.

7 Q. Rosenzweig, thank you. And you and I have not met before
8 today; correct?

9 A. That is correct.

10 Q. And, sir, you are no stranger to the courtroom; correct?

11 A. That is correct.

12 Q. And you have been testifying in litigation since 1990;
13 correct?

14 A. That is correct.

15 Q. And, in fact, you have given over 200 depositions;
16 correct?

17 A. I don't know if it's over 200, but probably over 100.

18 Q. Yeah. Somewhere in the vicinity of 100 to 200
19 depositions; correct?

20 A. That is correct.

21 Q. And when you were being deposed in those instances, you
22 were being paid by one side or the other to act as an expert
23 witness; correct?

24 A. That is correct.

25 Q. And today you are here acting as an expert witness;

—Rosenzweig - Cross - Monsour—

1 correct?

2 A. That is correct.

3 Q. And the plaintiffs have paid for your time; correct?

4 A. That is correct.

5 Q. And you mentioned before that you're -- I think it's
6 about three, three and a half hours of testimony today you
7 will charge \$10,000; correct?

8 A. That is correct.

9 Q. Now, your 10,000 a day charge, that didn't exist as of
10 May of this year; correct?

11 A. No, it did, yes.

12 Q. Well, isn't it true that in May of this year you
13 testified in another trial and your rate was \$5,000 a day?

14 A. Well, that was a pre, before I -- that trial had started
15 or that case had started before my rate had gone up, yes.

16 Q. Okay. So, but your rate for testifying in trial doubled
17 from \$5,000 to \$10,000 a day; correct?

18 A. That is correct.

19 Q. And, now, given that you've been doing this from 1990 up
20 until now -- now, you have actually -- in your business you
21 have actually created a separate corporation for your
22 litigation; correct?

23 A. No, I have not.

24 Q. Well, you have a separate business; correct?

25 A. No, that is my entire business.

Rosenzweig - Cross - Monsour

1 Q. All right. And do you have a particular name that you
2 use for your litigation consulting?

3 A. No, I do not.

4 Q. All right. And I know that you testified before that in
5 a given week you will do surgery on about a day to a day and a
6 half; correct?

7 A. That is correct.

8 Q. And then you said that you spend about two days,
9 sometimes a little bit more than two days on what you label as
10 administrative time. Is that fair?

11 A. That is correct.

12 Q. And the administrative time includes your litigation
13 activities; correct?

14 A. That is correct.

15 Q. And isn't it true, sir, that since you have been
16 consulting on mesh litigation, you have billed over
17 \$1 million?

18 A. I don't know what the exact figure is.

19 Q. Well, you testified before that you billed over \$900,000
20 consulting on mesh litigation; correct?

21 A. That is correct.

22 Q. And, so, that testimony was given -- I believe that was
23 given when you -- do you remember my partner who took your
24 deposition, Mr. Keenan?

25 A. That is correct.

—Rosenzweig - Cross - Monsour—

1 Q. All right. And he took your deposition I think about
2 five months ago. I can get you the exact date. But --

3 A. I think it was over the summer, but that's probably about
4 right.

5 Q. Okay. And just so I'm being clear, you're right. It was
6 in June of 2014; correct?

7 A. That is correct.

8 Q. And, obviously, you've been working on your consulting
9 work in mesh litigation after June of 2014 all the way up
10 until now; correct?

11 A. That is correct.

12 Q. And, so, is it fair to say that you've made approximately
13 a million dollars consulting in mesh litigation; correct?

14 A. That is correct.

15 Q. Now, -- Doctor, just for ease of time, I'm going to
16 put -- and I mean you no offense by this. I'm going to put
17 Dr. Rosen [sic] right now. It's -- it is R-o-s-e-n-z-w-e-i-g?

18 A. That is correct.

19 Q. Okay. I'll spell it all out. Okay. So, I've written
20 down \$1 million mesh litigation. We've already talked about
21 that; correct?

22 A. That is correct.

23 Q. Now, Mr. Monsour brought out that yesterday I showed this
24 jury an AUGS statement. And you recall the questions from Mr.
25 Monsour on that?

Rosenzweig - Cross - Monsour

1 A. That is correct.

2 Q. You've seen that statement before; correct?

3 A. Yes, I have.

4 Q. And you've been asked questions about it before. I think
5 Mr. Keenan asked you questions about it before; correct?

6 A. That is correct.

7 Q. And I don't want to pull it out, but I will if we need
8 to. But you'll agree with me that that is a statement that
9 was issued by five people and then approved by the AUGS Board
10 of Directors; correct?

11 A. That is correct.

12 Q. And what does AUGS stand for?

13 A. The American Urogynecologic Society.

14 Q. All right. And that is the largest society of
15 professionals like yourself in the United States; correct?

16 A. For urogynecologists, that is correct.

17 Q. And that, that statement -- and the jury will recall
18 that -- that it was stated that 99 percent of the members of
19 AUGS use polypropylene mid-urethral slings; correct?

20 A. That's what it states, but that actually is not what the
21 data shows.

22 Q. All right. Well, you'll agree with me that that's what
23 it states; correct?

24 A. That is correct.

25 Q. And you obviously are in that one percent of people in

—Rosenzweig - Cross - Monsour—

1 your industry that do not use polypropylene mid-urethral
2 slings; correct?

3 A. Well, sir, that statement is based on a study by Clemons.
4 And what Clemons did in that study --

5 Q. No, sir. Let's just go back to the statement. Mr.
6 Monsour will be able to ask you questions later.

7 MR. MONSOUR: Your Honor, I object. He's --

8 THE COURT: Let me hear this objection. Go ahead,
9 please, Mr. Monsour.

10 MR. MONSOUR: He asked him a question and he's
11 answering the question. He's not allowing him to complete his
12 answer.

13 MR. ADAMS: And I would move that his response was
14 nonresponsive and that's why I was rephrasing it, Your Honor.

15 THE COURT: All right, gentlemen, let's begin again.
16 Ask the question and, Doctor, you listen to it and answer it
17 directly.

18 BY MR. ADAMS:

19 Q. Sir, will you agree with me that the AUGS statement
20 states that 99 percent of its members use polypropylene
21 mid-urethral slings; correct?

22 A. That's what the statement says and it's based on a
23 survey.

24 Q. All right.

25 MR. ADAMS: And I move to strike everything except

—Rosenzweig - Cross - Monsour—

1 for "yes," Your Honor.

2 THE COURT: That motion is denied. The witness, I
3 believe, answered the question and gave his explanation and I
4 believe that's appropriate.

5 MR. ADAMS: That's fine.

6 BY MR. ADAMS:

7 Q. And, obviously, you fall in the one percent. And I
8 don't want to quibble with you about how the 99 is
9 derived. But you're in the one percent, or that group
10 of doctors who do not use mid-urethral slings; correct?

11 A. Well, it would be important for the jury to know actually
12 how that number was derived so that they could see that I am
13 not in the minority because the study actually threw out
14 respondents who did not use mid-urethral slings in coming up
15 with that 99 percent number.

16 If you read the study, the methodology excluded
17 respondents that did not use mid-urethral slings or did not do
18 pelvic organ prolapse surgery.

19 Another thing that they state is only 55 percent of
20 respondents -- of AUGS members actually responded to the
21 survey. And they say that this survey doesn't accurately
22 reflect the opinions of AUGS members at large.

23 MR. ADAMS: Move to strike as nonresponsive.

24 THE COURT: You have, Doctor, given your explanation,
25 I believe, prior to directly answering Mr. Adams' question.

—Rosenzweig - Cross - Monsour—

1 So, as we proceed I think it will be helpful to the jury, and
2 certainly to me, if you answer directly and then give an
3 explanation if you believe one is required.

4 THE WITNESS: I'll certainly do that.

5 THE COURT: In this instance, you gave the
6 explanation. I do not believe you answered it directly.

7 THE WITNESS: I would fall into the non-sling users,
8 yes.

9 BY MR. ADAMS:

10 Q. Right. And according to AUGS, that would be the
11 category other than the 99 percent that they listed;
12 correct?

13 A. That is correct.

14 Q. Which would be one percent; correct?

15 A. That is correct.

16 Q. Now, we've already talked about your work as an expert.
17 And you had -- Mr. Monsour had Ms. Blankenship stand up during
18 the examination. Do you recall that?

19 A. Yes, sir.

20 Q. And you know Ms. Blankenship lives here in West Virginia;
21 correct?

22 A. That is correct.

23 Q. And she went to see Dr. Lassere who is a very well
24 credentialed West Virginia doctor; correct?

25 A. That is correct.

—Rosenzweig - Cross - Monsour—

1 Q. He's one of your peers; correct?

2 A. That is correct.

3 Q. And you're not criticizing any of the work or any of the
4 counseling or any of the decisions that were made by Dr.
5 Lassere in this case; correct?

6 A. That is correct.

7 Q. And you know that neither is Boston Scientific's experts
8 criticizing any of the decisions or any of the work done by
9 Dr. Lassere in this case; correct?

10 A. That is correct.

11 Q. Now, you have never examined Ms. Blankenship yourself;
12 correct?

13 A. That is correct.

14 Q. You had not even met Ms. Blankenship until you came to
15 West Virginia for this trial; correct?

16 A. That is correct.

17 Q. The first time you met her or laid eyes on her was this
18 morning; correct?

19 A. That is correct.

20 Q. And, so, all of the opinions that you have been giving as
21 a paid expert since 1990 making over \$1 million in mesh
22 litigation is basically derived on looking at records and
23 reading depositions; correct?

24 A. That is correct.

25 Q. You have not engaged in any type of doctor/patient

—Rosenzweig - Cross - Monsour—

1 relationship with Ms. Blankenship; correct?

2 A. That is correct.

3 Q. And you would agree that when you treat one of your
4 patients for stress urinary incontinence, you engage in
5 multiple sessions of counseling and testing; correct?

6 A. That is correct.

7 Q. And you are in no position -- and, in fact, you would not
8 criticize any of the process that went on between Dr. Lassere
9 and Ms. Blankenship with respect to the decision that was made
10 to implant an Obtryx sling; correct?

11 A. That is correct.

12 Q. And, in fact, now when you've consulted in other
13 litigations -- you've done medical malpractice work; correct?

14 A. That is correct.

15 Q. And you'll agree with me that in the majority of the time
16 you have testified on behalf of a plaintiff who is suing a
17 doctor in litigation; correct?

18 A. That is correct.

19 Q. And, so, you have been paid before to actually be
20 critical and give testimony just like you're doing today from
21 the witness stand that is critical of a practicing physician.
22 Fair?

23 A. That is correct.

24 Q. And, so, practicing physicians include gentlemen like
25 Dr. Bhanot, Dr. Lassere, and Dr. Luby who are busy full-time

Rosenzweig - Cross - Monsour

1 seeing patients; correct?

2 A. That is correct.

3 Q. Now, when we talk about the doctors, like we'll take Dr.
4 Lassere, have you ever met him?

5 A. No, I have not.

6 Q. You haven't talked to him either; correct?

7 A. No, I have not.

8 Q. The only thing you've done is to read his deposition.
9 Fair?

10 A. And his medical records, yes.

11 Q. Fair enough. So, you reviewed his deposition and his
12 medical records; correct?

13 A. That is correct.

14 Q. And you'll agree with me that he was a very well -- or he
15 is a very well qualified doctor in a specialty field; correct?

16 A. That is correct.

17 Q. And you have testified before when you are acting on
18 behalf of a plaintiff suing a doctor that doctors have an
19 obligation to keep abreast of the scientific literature that
20 is in their field; correct?

21 A. That is correct.

22 Q. That's basic; correct?

23 A. That is correct.

24 Q. You learn that in medical school; correct?

25 A. That is correct.

—Rosenzweig - Cross - Monsour—

1 Q. You learn that every when you do your MCLE; correct?

2 A. MCLE?

3 Q. Well, your continuing -- your continuing education;
4 correct?

5 A. That is correct.

6 Q. My state calls it MCLE. What does your state call it?

7 A. It's Continuing Medical Education.

8 Q. Okay, all right. So, you learn from medical school and
9 then in your practice that you've got to keep abreast of the
10 literature; correct?

11 A. That is correct.

12 Q. And that is extremely important if you are a doctor
13 implanting a particular medical device into a patient;
14 correct?

15 A. That is correct.

16 Q. And you know that the three doctors at issue, you know --
17 well, by the way, did you read Dr. Bhanot's deposition?

18 A. No, I have not.

19 Q. Did you read Dr. Luby's deposition?

20 A. No, I have not.

21 Q. And, well, let's just assume that all three of those
22 doctors had been using mid-urethral slings for a couple of
23 years prior to the time that they treated these ladies in this
24 case. Okay?

25 A. Okay.

—Rosenzweig - Cross - Monsour—

1 Q. And you know that Dr. Lassere, his experience was that he
2 actually started using mid-urethral slings back in the 1990s;
3 correct?

4 A. I would not argue with that.

5 Q. Okay. And the jury's already seen the timeline of sling
6 devices. You will agree with me that the original concept of
7 a mid-urethral sling was actually created by doctors who cut
8 off pieces of mesh and then used them, basically custom cut
9 them and used them in operations; correct?

10 A. That is correct.

11 Q. And then what happened is that in like 1998 the TVT was
12 created by Johnson & Johnson or Ethicon and that basically was
13 a custom cut piece of polypropylene mesh; correct?

14 A. It was actually earlier than that, but that's about
15 correct.

16 Q. All right. How much earlier then? And I'll take your
17 correction.

18 A. '96, '97.

19 Q. Okay. So, '96, '97 the TVT comes out and that is a
20 commercially available product; correct?

21 A. That is correct.

22 Q. And that product obviously is lawfully sold and can be
23 used by doctors like yourself who are allowed to write a
24 prescription; correct?

25 A. You don't have to write prescription for it. It's

—Rosenzweig - Cross - Monsour—

1 actually purchased by the hospital and then you use that. So,
2 the hospital is the one that actually purchases it.

3 Q. Fair enough. And, so, let's go back to Dr. Lassere. He
4 started using these mid-urethral slings back sometime in the
5 '90s. And the jury will hear his testimony later. But you're
6 familiar with that; correct?

7 A. That is correct.

8 Q. And then he used a number of different mid-urethral
9 slings. And then eventually he started using the Obtryx.
10 Correct?

11 A. That is correct.

12 Q. And you know that that -- Dr. Lassere, like any doctor,
13 including yourself, has an obligation to keep up on the
14 medical literature regarding the products that they put in
15 people's bodies; correct?

16 A. That is correct.

17 Q. And, so, Dr. Lassere -- and, again, I think his
18 deposition reflects this -- he was fully aware of all of the
19 information in the scientific literature about the safety and
20 efficacy of the products that he was putting inside people's
21 bodies; correct?

22 A. Well, I think that the jury will get to hear his direct
23 testimony.

24 Q. Okay, fair enough. You believe that a doctor should do
25 that, though; correct?

—Rosenzweig - Cross - Monsour—

1 A. That is correct.

2 Q. All right. And, so, if Dr. Lassere was doing his job, he
3 would have been keeping abreast of all of the scientific
4 literature on the devices that he put in people's bodies;
5 correct?

6 A. That is correct.

7 Q. All right. So, now, you said before -- you were talking
8 about degradation, shrinkage and contracture. Do you recall
9 that?

10 A. Yes, sir.

11 Q. Those are the problems that you believe exist with
12 polypropylene mesh; correct?

13 A. Including deformation, yes.

14 Q. All right. And let's just talk about degradation,
15 shrinkage, and contracture and we'll come back to deformation
16 in a little bit. Okay?

17 A. Okay.

18 Q. Now, you said before that in the 1970s there was
19 literature out talking about the problems of using mesh in
20 people's bodies; correct?

21 A. No. I was stating that in the '70s was when the basic
22 science research came out about what things, what chemicals
23 like peroxides and acids can degrade polypropylene.

24 Q. Okay. So, but in the '70s there's information about
25 peroxides and acids degrading polypropylene; correct?

—Rosenzweig - Cross - Monsour—

1 A. That is correct.

2 Q. And that information is known out in the scientific
3 community; correct?

4 A. If you look for it, yes, you should be able to find it.

5 Q. Okay. By the way, all of the articles we've been talking
6 about, and this Cholhan article and the Ross article that Mr.
7 Monsour talked about, those are available in journals for
8 doctors to read; correct?

9 A. That is correct.

10 Q. And, so, in particular Ross and Cholhan, those are in
11 the -- isn't it the ACOG journal?

12 A. Well, yes, the obstetrics and gynecology -- what we call
13 the green journal because it has a green cover on it.

14 Q. Exactly. And it's the green journal and it's probably
15 one of the most widely read journals by doctors in your field;
16 correct?

17 A. That is correct.

18 Q. You would have expected that all of the three doctors
19 that were implanting medical devices and practicing in your
20 area would have been reviewing that journal; correct?

21 A. That is correct.

22 Q. And that journal included the Ross article and the
23 Cholhan article; correct?

24 A. Well, actually the Cholhan article is in the *American*
25 *Journal of Obstetrics and Gynecology* and that's called the

—Rosenzweig - Cross - Monsour—

1 gray journal because it used to have a gray cover on it.

2 Q. Fair enough. But the same thing goes true with respect
3 to the questions that we talked about the green journal. It
4 applies to the gray journal. Doctors should read those;
5 correct?

6 A. That is correct.

7 Q. All right. And you, sir, you from time to time -- you
8 were talking about your history in dealing with the TVT;
9 correct?

10 A. Yes.

11 Q. And when you were dealing with the TVT -- and let me, let
12 me slow down and back up. The TVT is the same device that
13 we've talked about that first came out on the market in '76,
14 '77?

15 A. Actually, '96.

16 Q. '96, '97. And when that device came out, it was
17 introduced by Ethicon or Johnson & Johnson; correct?

18 A. That is correct.

19 Q. And you've talked about how you've actually used that
20 device; correct?

21 A. That is also correct.

22 Q. And you had experience, obviously, before in dealing with
23 sales reps from companies like Ethicon or Johnson & Johnson;
24 correct?

25 A. That is correct.

—Rosenzweig - Cross - Monsour—

1 Q. Sales reps from time to time will talk to you about the
2 advantage of their products like the TVT; correct?

3 A. That is correct.

4 Q. And you'll agree with me that you as a medical doctor
5 would never allow any kind of advice by a sales representative
6 to replace your professional judgment; correct?

7 A. That is correct.

8 Q. Because at the end of the day, you are the person that is
9 responsible for making the decision as to whether to guide
10 your patient towards a particular medical device or not;
11 correct?

12 A. That is correct.

13 Q. And, so, regardless of what a sales rep tells you,
14 regardless of the information that a sales rep gives you,
15 you're going to do your homework and you're going to make sure
16 that that device is safe and it's effective before you put it
17 in a woman's body; correct?

18 A. As best you can, yes.

19 Q. And that's what you did back before you decided to put
20 the TVT in a woman's body; correct?

21 A. That is correct.

22 Q. And you started putting the TVT into women's bodies back
23 in 2003; correct?

24 A. Correct.

25 Q. And, so, as of 2003, you had done all your homework. You

—Rosenzweig - Cross - Monsour—

1 had looked at the literature. And you were secure in your
2 belief that the TVT was a safe and effective product for the
3 people that you were going to put it in their bodies in;
4 correct?

5 A. That isn't actually completely correct. I still had some
6 trepidation about it. I initially started using it in
7 replacement for my pubovaginal slings. And I didn't -- we
8 didn't get into this earlier, but -- I think I might have. I
9 used a pubovaginal sling as a rescue operation for women that
10 have severe recurrent stress urinary incontinence that there
11 are very few other alternatives. And I moved to the TVT as a
12 replacement for, to see if it was a good replacement for my
13 pubovaginal slings.

14 Q. Okay. You talked about trepidation. Did you tell any of
15 your patients back in 2003 before you put the TVT into their
16 bodies that, you know, "I've got a little trepidation about
17 this device that I'm going to put in your body"?

18 A. That is correct.

19 Q. You did do that?

20 A. That is correct.

21 Q. All right. And did you then inform every single one of
22 those patients after that point in time about that
23 trepidation?

24 A. I have a very honest discussion with my patients about
25 what is known and what isn't known. I wrote a paper back in

—Rosenzweig - Cross - Monsour—

1 the late '80s, early '90s on the pubovaginal sling. And one
2 of the concerns that I started to have was just that, if there
3 are more complications associated with using a synthetic
4 material and maybe trying to find a better synthetic material
5 to use.

6 Q. Fair enough. You mentioned papers. You have not
7 authored any articles on mid-urethral slings or polypropylene
8 devices; correct?

9 A. That is correct.

10 Q. And you talked about --

11 A. Yes, that is correct.

12 Q. All right. So, and let me break that down. You haven't
13 authored any papers on polypropylene mid-urethral slings;
14 correct?

15 A. That is correct.

16 Q. And you haven't authored any papers on polypropylene
17 medical devices; correct?

18 A. That is correct.

19 Q. Okay. And I'm just going to put "no papers PP devices."
20 Now -- and, so, you're familiar with the peer-review process;
21 correct?

22 A. That is correct.

23 Q. And you know that as part of the peer-review process,
24 somebody's opinions have to be reviewed by somebody else to
25 make sure that they are scientifically valid; correct?

Rosenzweig - Cross - Monsour

1 A. Someone's opinions or the, the study that is about to be
2 published?

3 Q. The study.

4 A. Yes. You look at, you look at their methods that they
5 use, the results to make sure that the methods actually show
6 the results. And then you look at their discussion to see if
7 their conclusions are actually validated by their methodology.

8 Q. Right. So, if a person writes a paper and they put forth
9 data and then draw conclusions from it, that literature, in
10 order for it to be published, goes through a peer review
11 process where it's reviewed by people. And then ultimately
12 they decide whether to accept it or reject it. Correct?

13 A. That is correct.

14 Q. And you have never had any of the opinions that you've
15 given in this courtroom peer-reviewed as part of that process;
16 correct?

17 A. As part of what process? I haven't published any studies
18 about the opinions that I've been given. So, it wouldn't go
19 through the peer-review process.

20 Q. Right. That's my simple point. The opinions that you've
21 offered concerning degradation, contracture, and other
22 problems with polypropylene, you've never authored a paper on
23 that and published it in a peer-reviewed journal. Agreed?

24 A. That is correct.

25 Q. Okay. Now, we were talking about your use of the TVT.

—Rosenzweig - Cross - Monsour—

1 And you had originally started using the TVT in 2003; correct?

2 A. That is correct.

3 Q. And then from 2003 to 2005 you continued to use that
4 product; correct?

5 A. That is correct.

6 Q. And you have testified before that during that time
7 period, you implanted approximately 20 TVT devices; correct?

8 A. Approximately 15 to 20, yes.

9 Q. Okay. And then from 2005 to 2007 you switched and
10 started to use the TVT-O; correct?

11 A. Well, I actually did my first TVT Obturator in 2004.

12 Q. Okay. And you stopped using the TVT-O in 2007; correct?

13 A. That is correct.

14 Q. And you implanted 40 to 50 TVT-Os; correct?

15 A. That is correct.

16 Q. All right. Now, so, let me draw that out real quickly
17 just so the jury will have that. Okay. I've done my best
18 chicken scratching here. Can you see that?

19 A. Yes, sir.

20 Q. Okay. And we've already established from '03 to '05 you
21 did 20 TVTs; correct?

22 A. 15 to 20, yes.

23 Q. All right. Let me write that down, 15 to 20. And then
24 from '05 to '07 you did 40 to 50 TVT-Os; correct?

25 A. That is correct.

—Rosenzweig - Cross - Monsour—

1 Q. All right. And you, sir, when we talk about degradation,
2 shrinkage, and contracture, you are not representing to this
3 jury that you are an expert in material science. Fair?

4 A. That is correct.

5 Q. And you have -- obviously, you're a medical doctor and
6 you have a medical degree; correct?

7 A. That is correct.

8 Q. That takes a lot of time and a lot of intelligence to do
9 that. Correct?

10 A. Thank you.

11 Q. Well, do you agree?

12 A. Yes, sir.

13 Q. So, you know that in this case, for example, there are
14 material science experts who actually study polypropylene and
15 how it behaves in the human body; correct?

16 A. That is correct.

17 Q. And I believe you indicated that your experience with how
18 polypropylene behaves in the human body, one aspect that you
19 rely upon is the fact that you've actually, according to you,
20 have observed it first-hand when you have done these explants
21 or removals; correct?

22 A. That is correct.

23 Q. And, so, you described to Mr. Monsour how when you
24 started doing removals you noticed immediately that the mesh
25 had degraded and shrunk and contracted; correct?

—Rosenzweig - Cross - Monsour—

1 A. I don't know whether it was immediately afterwards, but I
2 noticed changes that were, that it was hard and brittle and
3 cracked, yes.

4 Q. All right. And, in fact, sir, you have testified before
5 that the first time that you did a mesh removal in 2003, you
6 realized that polypropylene degraded; correct?

7 A. If I testified to that, that I saw it, that there were
8 cracks in the polypropylene, then, yes.

9 Q. Okay. So, 2003 you make that observation. And I'll put
10 kind of a little window around there so I'm not holding you to
11 the exact date. But sometime around when you did the first
12 removal you knew polypropylene degraded; correct?

13 A. No, I made an observation that that was what I was
14 seeing.

15 Q. And you -- obviously, you were familiar with the
16 literature on polypropylene at that point; correct?

17 A. That is correct.

18 Q. And then, sir, you have -- and, in fact, even as, after
19 2003, shortly after that you did a couple more removals;
20 correct?

21 A. I've been doing removals since that time, yes.

22 Q. And you were concerned enough that you've testified
23 before that actually you reported degradation or problems with
24 the mesh to the Ethicon representative; correct?

25 A. That is correct.

—Rosenzweig - Cross - Monsour—

1 Q. And you actually made the effort to say, "There is a
2 concern that I have with your mesh and I believe it's
3 degrading." Correct?

4 A. I said that there was a concern with the mesh, yes. And
5 these were the problems that the patients were coming in with.

6 Q. Okay. But those same concerns didn't stop you from
7 continuing to implant the device in somewhere around 55 to the
8 high end of 70 women; correct?

9 A. That -- because that understanding was starting to evolve
10 what the problem was, yes.

11 Q. And, so, this problem that you've talked about about
12 degradation, shrinkage, and contracture, you believe that
13 occurs with all polypropylene mesh; correct?

14 A. That is correct.

15 Q. All polypropylene mesh used in any mid-urethral sling is
16 subject to degradation, shrinkage, and contracture; correct?

17 A. That is correct.

18 Q. And all polypropylene mesh that is used in mid-urethral
19 slings is defective according to you; correct?

20 A. That is correct.

21 Q. And, so, in this case, you're not singling out the Obtryx
22 and saying that somehow the mesh in the Obtryx is unusual or
23 different than the mesh in the TVT or in the MonArc or in the
24 SPARC or in any of the other 62 devices that are out on the
25 marketplace; correct?

—Rosenzweig - Cross - Monsour—

1 A. There are differences in the polypropylene. There are
2 differences in the configuration of the weave patterns or the
3 knitting patterns. There's a difference in density. There's
4 a difference in fiber diameter. There's a difference in pore
5 size. There's a difference in the way the mesh is cut.
6 There's a difference in how it's heat-sealed.

7 So, yes, there will be differences in there. But my
8 statement is the polypropylene is not suitable for a permanent
9 implantation as a permanent device to treat stress urinary
10 incontinence.

11 Q. Right. So, regardless of the weave, regardless of the
12 density, regardless of all of those factors that you
13 mentioned, all of the products that consist of polypropylene
14 mesh are defective according to you; correct?

15 A. That is correct.

16 Q. And I've written down -- just to be fair, I've written
17 down, Dr. Rosenzweig, all polypropylene mesh -- all
18 polypropylene mid-urethral slings are defective. Fair?

19 A. That is correct.

20 Q. And you haven't done any type of study on the Obtryx
21 polypropylene mesh to distinguish it from any of the other
22 meshes used in the mid-urethral slings; correct?

23 A. What do you mean by study?

24 Q. Well, can you tell me -- well, let's do this. You'll
25 agree with me that all of the mid-urethral slings that are

—Rosenzweig - Cross - Monsour—

1 currently being used by doctors are macroporous monofilament
2 devices; correct?

3 A. It all depends on how you define macroporous. According
4 to an old classification by a gentleman named Ahmet who made
5 his classification in the '90s, anything over 75 microns,
6 which is 0.7 millimeters, is macroporous. Some of the newer
7 definitions say that macroporous has to be over one
8 millimeter.

9 Q. All right. And you'll agree with me that the, the Obtryx
10 is a macroporous monofilament mesh; correct?

11 A. Its pore size is slightly over a millimeter.

12 MR. MONSOUR: Objection.

13 THE COURT: Objection. Go ahead and state it,
14 please.

15 MR. MONSOUR: I was not allowed to ask about pore
16 size and now he's asking about pore size.

17 MR. ADAMS: I only asked if it's in the
18 classification of macroporous monofilament.

19 THE COURT: I sustain the objection. Let's go
20 forward, counsel.

21 MR. ADAMS: All right.

22 BY MR. ADAMS:

23 Q. So, are you, sir, able to tell us how the Obtryx
24 mesh is in any way different than the mesh used in
25 Ethicon's TVT?

—Rosenzweig - Cross - Monsour—

1 A. Well, they both have the same density. There is a
2 difference in the additives that each company puts into their,
3 into their polypropylene.

4 So, polypropylene isn't just a, a carbon and a hydrogen
5 put together. There are other things that are put in such as
6 antioxidants and stabilizers and plasticizers. There's a
7 difference in the color between the TVT and the Obtryx. One
8 has an additive that gives it a blue color. This is a white
9 color. So, there are differences in the chemical makeup of
10 the polypropylene.

11 Q. Okay.

12 A. Another difference is that the center portion is
13 heat-sealed so that the little edges that look like barbs are
14 taken off in the center portion. The TVT is made by either
15 cutting it mechanically where you get the barbed edges or cut
16 with a laser so that you don't have the barbed edges. So,
17 there are a lot of differences between the various products.

18 Q. And you've been critical of the TVT device because you
19 believe that the cutting of that device induces fraying;
20 correct?

21 A. That is correct. When you mechanically cut the mesh, the
22 edges actually break off and there's a fraying that takes
23 place.

24 Q. And you've talked in other settings that that fraying can
25 be dangerous when it's implanted in a woman; correct?

Rosenzweig - Cross - Monsour

1 A. That is correct.

2 Q. Besides fraying, the mechanical cutting on TVT devices
3 can also create particle loss; correct?

4 A. That is correct. Actually, we saw that today when I was
5 pulling on the, on the Obtryx sling. You could see particles
6 falling off of the mesh itself.

7 Q. All right. You know that with the Obtryx sling, with
8 that mesh the edges have been heat-sealed; correct?

9 A. Only in the center four sonometers of the mesh. The
10 rest -- as you can see, you have the edges which are called
11 tangs. Only the central portion of the mesh has been detanged
12 or those little edges have been taken off.

13 Q. All right. And detanged -- the, the purpose of
14 heat-sealing with the detang is to prevent fraying and
15 particle loss; correct?

16 A. And one of the ideas is that it makes it less elastic so
17 that it won't rope and curl. That's the thought behind using
18 a laser-cut mesh is that it makes the mesh stiffer. But that
19 actually causes a problem because it increases the erosion and
20 it increases the obstruction due to the, the stiffness of the
21 mesh.

22 Q. All right. And let's talk about -- it's a good sign when
23 I'm ticking these off, Doctor.

24 A. That is, sir.

25 Q. Now, when you did your implants on these women, we've

—Rosenzweig - Cross - Monsour—

1 already established that you did your first removal and saw
2 the degradation in 2003. Do you recall that?

3 A. That is correct, sir.

4 Q. And then you go on to implant these devices all through
5 2007; correct?

6 A. That is correct.

7 Q. And you'll agree with me that every single time that you
8 would implant a medical device in a woman's body, you would
9 engage in a risk benefit analysis for that particular
10 situation; correct?

11 A. That is correct.

12 Q. And you'll agree with me that that is a very important
13 process that each doctor who is implanting a medical device
14 has to engage in; correct?

15 A. That is correct.

16 Q. And you're not here to criticize that process that was
17 engaged in by Dr. Lassere or Dr. Bhanot and Dr. Luby; correct?

18 A. That is correct.

19 Q. And you know from Dr. Lassere's deposition that he had a
20 good experience in his patients in using the Obtryx device;
21 correct?

22 A. That is correct.

23 Q. In fact, you've talked about problems related to the
24 devices. Dr. Lassere, who we've established who was a --
25 strike that. Dr. Lassere you know -- we've established in the

—Rosenzweig - Cross - Monsour—

1 1990s he started using the TVT; correct?

2 A. That is correct.

3 Q. And sometime --

4 A. We know it's from the late '90s because we've already
5 established when the TVT first came to the market here in the
6 United States.

7 Q. I put "late" up there.

8 A. Thank you, sir.

9 Q. And we know that -- do you remember the time period in
10 which he moved to the Obtryx?

11 A. We know the Obtryx was first released in 2004. So, it
12 must have been after 2004.

13 Q. Okay. So, I'm just going to put post 2004 he uses the
14 Obtryx; correct?

15 A. That is correct.

16 Q. And you'll agree with me that Ms. Blankenship was not the
17 first patient that he used the Obtryx on; correct?

18 A. That is also correct.

19 Q. And, in fact, he had a history of using that product in
20 his patients a pretty good time before; correct?

21 A. Well, we know that it was released in 2004, and I think
22 he'll probably testify to this jury exactly when he started
23 using it.

24 Q. Okay, fair enough. And you'll agree with me that his
25 experience and the results of his patients were excellent

—Rosenzweig - Cross - Monsour—

1 according to him; correct?

2 A. That's what he says. But, actually, there's a little bit
3 of a problem with using your own personal experience from what
4 we know in the literature.

5 Q. Well, my question was Dr. Lassere says his experience was
6 excellent; correct?

7 A. That's what he testified to, yes.

8 Q. All right. And he said that as far as complications, he
9 had a one percent erosion rate; correct?

10 A. That is what he said. And, again, if you look at the
11 literature, there are problems with looking at individual
12 physicians' experience.

13 Q. We will get through this faster --

14 A. Okay.

15 Q. -- if you can answer my question.

16 A. Yes, sir.

17 Q. He said he had a one percent erosion rate; correct?

18 A. That is correct.

19 Q. And he said that Ms. Blankenship has been his only case
20 involving long-term complaints about dyspareunia; correct?

21 A. That is correct.

22 Q. I put "one incident of dyspareunia." Do you see that,
23 Doctor? I want to be fair to you.

24 A. That is correct. I can't see it, but I saw you writing.
25 Thank you.

—Rosenzweig - Cross - Monsour—

1 Q. Okay. And, so, again, based upon Dr. Lassere's clinical
2 experience, you would agree with me that he had every reason
3 in the world to continue using the Obtryx and he did; correct?

4 A. That is correct.

5 Q. And, in fact, he even continued to use the Obtryx after
6 he was implanting it -- after he implanted it in Ms.
7 Blankenship; correct?

8 A. That is correct.

9 Q. He's performed approximately 50 Obtryx surgeries;
10 correct?

11 A. That is correct.

12 Q. And according to him -- now, you talked about the Burch
13 procedure and pubovaginal slings. Do you recall that?

14 A. Yes, sir.

15 Q. And the jury's already heard, and I don't want to go
16 through it, but you would agree with me that the AUGS
17 statement and other industry statements talk about the
18 advantages of mid-urethral slings over the Burch procedure or
19 pubovaginal slings; correct?

20 A. In the short-term, yes.

21 Q. All right. And according to Dr. Lassere, he believes
22 that mid-urethral slings is superior to the Burch procedure;
23 correct?

24 A. That is his opinion, yes.

25 Q. And he's the guy on the ground dealing with Ms.

—Rosenzweig - Cross - Monsour—

1 Blankenship when she's having these severe SUI problems and
2 he's the one advising her; correct?

3 A. In this case, yes.

4 Q. And he's doing his best. He's keeping up on the
5 literature and he wants a good result for her. Correct?

6 A. That is correct.

7 Q. And, so, the fact that the Burch procedure takes a bit
8 longer in time was of no factor to Dr. Lassere when he's
9 trying to get the best result for his patient; correct?

10 A. I believe that's something you would have to ask him.

11 Q. Okay. Well, you'll agree with me that that shouldn't be
12 a factor; correct?

13 A. No, the long-term complication rate and the success rate
14 should be a factor that's taken into consideration.

15 Q. All right. Let's talk about the Burch procedure. The
16 Burch procedure that you've done, you'll agree with me that
17 the disadvantage -- when you're comparing mid-urethral slings
18 to the Burch procedure, one of the disadvantages is that the
19 Burch procedure is a longer operation; correct?

20 A. That is correct. It takes me about 30 minutes to 40
21 minutes to do compared to about 20 minutes.

22 Q. All right. And it often involves general anesthesia;
23 correct?

24 A. That is correct. But it can be and has been described as
25 being done under local.

—Rosenzweig - Cross - Monsour—

1 Q. And often women have to stay in the hospital one to two
2 days; correct?

3 A. That is correct.

4 Q. And these doctors -- you know, Dr. Lassere described how
5 he's able to do an implant or a surgery with an Obtryx in
6 about 30 minutes or less; correct?

7 A. That is correct.

8 Q. And it doesn't involve a hospital stay; correct?

9 A. Most of the patients that I see that have had slings
10 spend one night in the hospital, but it can be done as an
11 out-patient, yes.

12 Q. And it can be done without any type of general
13 anesthesia; correct?

14 A. That is correct.

15 Q. And then as far as the recovery time, you've seen it in
16 the scientific literature. It talks about how there are more
17 comorbidities associated with the Burch than mid-urethral
18 slings in general; correct?

19 A. Comorbidities?

20 Q. It's more morbidities associated.

21 A. Because comorbidities are things like hypertension and
22 diabetes.

23 Q. Okay. You know it involves more morbidity; correct?

24 A. Short-term, yes.

25 Q. Okay. And we saw the Obtryx operation. And you, you

—Rosenzweig - Cross - Monsour—

1 know, I'll have to be candid with you. The first time that I
2 got involved in this and I saw that procedure, it, it is kind
3 of gory and I'm not used to it. And you understand that's a
4 common reaction to a layperson; correct?

5 A. Watching surgery, yes.

6 Q. Okay. And -- but if I were to come in -- if we were to
7 take the time for me to show this jury -- we can do it, but if
8 I was going to show this jury one of these Burch procedures,
9 we would be showing that the doctor makes an incision or cut
10 on the bikini line; correct?

11 A. That is correct.

12 Q. And when you do the Burch procedure, you do an open Burch
13 as opposed to laparoscopic; correct?

14 A. That is correct.

15 Q. And, so, in order -- after you make that incision, you
16 have to spread open the area that you are going to operate in;
17 correct?

18 A. With small retractors, yes.

19 Q. Okay. And, so, again, to a layperson if we were going to
20 take the time, watching the Burch procedure is not going to be
21 anymore pleasant than watching the Obtryx procedure; correct?

22 A. More likely than not, yes.

23 Q. Okay. And the device is the trocars. Now, to a
24 layperson when you're looking at a trocar and seeing it for
25 the first time, it seems a little bit unusual. You'll agree

Rosenzweig - Cross - Monsour

1 with that?

2 A. Trocars look rather archaic and barbaric the first time
3 you see them, yes.

4 Q. But there's devices, for example, like the Capio device.
5 That's another long device with a big needle that reaches
6 down. You use that in surgery; correct?

7 A. That is correct. It is a long device, but it has a
8 fairly small needle at the end of it.

9 Q. Okay. And, so, those devices like trocars, they're used
10 in other surgeries besides implanting of mid-urethral slings;
11 correct?

12 A. That is correct.

13 Q. All right. So, it's a common -- not a common, but it's a
14 fairly common surgical tool that is used in other operations
15 besides even a mid-urethral sling; correct?

16 A. Trocars, yes.

17 Q. Now, Ms. Blankenship. You'll agree with me that when she
18 went to Dr. Lassere, she was having life-altering conditions
19 from stress urinary incontinence; correct?

20 A. Life-altering?

21 Q. Yes.

22 A. I would say it impacted her quality of life. But when I
23 use the term "life-altering" it means that there is a chance
24 that someone could, could die from it.

25 Q. All right. So, she had -- you will agree with me that

—Rosenzweig - Cross - Monsour—

1 she had very, let's say, severe important-to-her quality of
2 life issues; correct?

3 A. It did impact her quality of life, yes.

4 Q. You read her deposition?

5 A. Yes, I did.

6 Q. Prior to -- her SUI got to the point where in 2006 and
7 2007 she was wearing two to three pads a day; correct?

8 A. That is correct.

9 Q. 2008, 2009 there was an increased frequency and quantity
10 of stress urinary incontinence; correct?

11 A. That is correct.

12 Q. By the time she was visiting with Dr. Lassere, she was
13 wearing adult diapers from time to time; correct?

14 A. That is correct.

15 Q. And she was actually developing irritation which would
16 cause a burning like sensation on her, on her skin from having
17 the wet pads; correct?

18 A. That is what she described, yes.

19 Q. And there is no question that she made the decision,
20 along with Dr. Lassere, that she didn't want to live that way
21 anymore and she was willing to consent to the risk of a
22 surgery; correct?

23 A. That is correct.

24 Q. And you'll agree with me that Dr. Lassere, who was
25 keeping up on the medical literature and had read the DFU from

—Rosenzweig - Cross - Monsour—

1 Boston Scientific, informed Ms. Blankenship of all of the
2 risks that he knew about from that material; correct?

3 A. I think that's what he's going to testify to, yes.

4 Q. And you've talked about that after the operation she has
5 suffered from dyspareunia; correct?

6 A. That is correct.

7 Q. He told her about that risk; correct?

8 A. That is correct.

9 Q. And she's also had urinary problems regarding urinary
10 retention after the operation; correct?

11 A. She's got dysfunctional voiding. We haven't seen that
12 she's been retaining urine, but she just has a very -- it
13 takes her a very long time to empty her bladder.

14 Q. Okay.

15 A. Her bladder is not emptying effectively.

16 Q. Dr. Lassere told her about the risks of dysfunctional --
17 it's actually called voiding dysfunction in the DFU; correct?

18 A. Correct.

19 Q. And he actually told her that she may have pain, pelvic
20 pain as a result of this procedure; correct?

21 A. That is correct.

22 Q. And all of those risks that he told her about, according
23 to the plaintiffs, have occurred; correct?

24 A. That is correct.

25 Q. And she consented in that document that she signed to

—Rosenzweig - Cross - Monsour—

1 accept those risks for the benefit that could occur by having
2 the surgery with the mid-urethral sling; correct?

3 A. For the surgical consent, yes.

4 Q. And, now, you're familiar with the process when --
5 obviously in litigation when a doctor may be sued for a
6 procedure. You've acted as an expert in those cases; correct?

7 A. That is correct.

8 Q. Now, when a doctor tells a patient about all of the risks
9 that are associated with a device and the patient consents to
10 the operation and then the patient has one of those exact
11 complications, you'll agree with me that there's no basis for
12 a suit against the doctor; correct?

13 A. Well, it all depends on -- I mean, just about every
14 complication is known. What becomes important is: Is it a
15 reasonable complication? So that is there some factors that
16 took place during the procedure that made it unreasonable for
17 this woman to have a complication. So that just because it's
18 a known complication doesn't make it a reasonable
19 complication.

20 Q. Okay. My simple question was you don't believe there's
21 any basis for any lawsuit against Dr. Lassere; correct?

22 A. In this case?

23 Q. Yes.

24 A. No.

25 Q. And -- by the way, before you came to testify in this

—Rosenzweig - Cross - Monsour—

1 case, you understand that this case involves four women;
2 correct?

3 A. That is correct.

4 Q. And those four women were treated by three different
5 doctors who all live right here in West Virginia; correct?

6 A. That is correct.

7 Q. And these doctors -- I don't want to cover every single
8 one of them. But you'll agree with me that they are all very
9 well qualified board certified physicians like yourself;
10 correct?

11 A. I'll make that assumption, yes.

12 Q. And did you -- when doctors are making a decision about
13 the risks and benefits of a medical device, you would agree
14 with me that their clinical experience is extremely important
15 to them in evaluating the safety of the device; correct?

16 A. Their clinical experience is important, yes.

17 Q. All right. And, so, even if there are articles saying,
18 "This medical device is the greatest thing since sliced
19 bread," if you as a doctor are having some complications in
20 your clinical experience in your practice, then you might want
21 to reject what the article says and go ahead and use it;
22 correct? Or go ahead and stop using it; correct?

23 A. Correct.

24 Q. All right. And, so, even if there were great articles
25 out about a particular medical device, a doctor has to use his

—Rosenzweig - Cross - Monsour—

1 own clinical experience based upon his patients to ultimately
2 make the call as to whether they're going to continue to use
3 the product; correct?

4 A. If it can be reasonably assumed that the doctor is going
5 to see all of the negative problems associated with the
6 device.

7 Q. All right. And when these papers are put together that
8 we've talked about like the Cholhan study that Mr. Monsour
9 asked you questions about, that involved how many patients?

10 A. Somewhere around 50.

11 Q. You want to check again? I think it was --

12 A. Or --

13 Q. Or 24?

14 A. 24, yes.

15 Q. Okay.

16 A. Thank you.

17 Q. So, --

18 MR. MONSOUR: Objection.

19 THE WITNESS: Well, actually, there were 53 --

20 THE COURT: Just a second. There's an objection.

21 Let me hear your objection.

22 MR. ADAMS: If it's a correction on the number, I'm
23 willing to accept it.

24 THE COURT: Well, we won't know until we hear it. Go
25 ahead, please.

—Rosenzweig - Cross - Monsour—

1 MR. MONSOUR: You got the number wrong.

2 MR. ADAMS: Okay. Would you tell me?

3 THE WITNESS: The study actually had --

4 THE COURT: Just a moment, sir, until we get this
5 resolved.

6 THE WITNESS: I'm sorry.

7 MR. ADAMS: I'm sorry. There were 25.

8 THE WITNESS: Well, 25 in the obturator article.
9 There's 53 total in the study, yes.

10 BY MR. ADAMS:

11 Q. So, do you have the study up there, Doctor?

12 A. Yes, I do.

13 Q. It says a total of 25 TO sling patients and 28 RP
14 patients; correct?

15 A. That is correct.

16 Q. So, Cholhan -- when I say TO, that's the transobturator
17 sling; correct?

18 A. That is correct.

19 Q. And we've established that the Obtryx is in the class of
20 devices called transobturator slings; correct?

21 A. That is correct.

22 Q. And you've already explained that that's because of the
23 way it's attached through the obturator foramen; correct?

24 A. That is correct.

25 Q. And, so, Cholhan was evaluating 25 Obtryx and then the --

—Rosenzweig - Cross - Monsour—

1 comparing that to 28 retropubic slings; correct?

2 A. That is correct.

3 Q. And I'll put 28 RP. And you've talked about how Cholhan
4 made some comments concerning this, the safety and
5 effectiveness of the Obtryx device; correct?

6 A. That is correct.

7 Q. Now, before you came in to testify, did you calculate or
8 even run some rough numbers as to what the collective
9 experience of these three doctors in West Virginia was with
10 respect to their use of the Obtryx?

11 A. Before I came in today?

12 Q. Yes.

13 A. I think that in your opening slide they had done six or
14 seven hundred.

15 Q. Okay. And when did you look at my opening slides?

16 A. Those were provided to me yesterday.

17 Q. Okay. Provided to you by the plaintiffs?

18 A. That is correct.

19 Q. You weren't here, obviously, during the opening
20 statements.

21 A. No, I was not.

22 Q. Okay. And, so, you know that they all placed
23 collectively 550 to -- what was the number -- 700 Obtryx
24 slings?

25 A. That's just a recollection.

—Rosenzweig - Cross - Monsour—

1 Q. Okay.

2 MR. MONSOUR: Your Honor, can I approach?

3 THE COURT: Yes, sir.

4 (The following occurred at sidebar.)

5 MR. MONSOUR: Does this mean I get to go into every
6 lawsuit that's been made against every one of these doctor so
7 I can show the complaint profile to adequately come up with a
8 study?

9 THE COURT: The objection specifically is as to which
10 question, counsel?

11 MR. ADAMS: It's not an objection I don't think.

12 THE COURT: Well, it might be if you let me hear it.

13 MR. ADAMS: Yes.

14 THE COURT: Go ahead.

15 MR. MONSOUR: I'm objecting to him going into the --
16 Judge Eifert already ruled that these doctors talking about
17 things being safe and effective is out. They can talk about
18 all these issues. He is opening a door and I'm giving -- this
19 is more of an alert than an objection. I'm going to want to
20 proceed with every claim that has been made against these
21 doctors collectively since he has opened the door into it. He
22 has opened the door into this. He has opened the door into
23 all the people that Dr. Rosenzweig has examined at every
24 single litigation.

25 This cross-examination has opened the door so wide

—Rosenzweig - Cross - Monsour—

1 open, Your Honor, that my redirect is going to go into some
2 areas that -- I'm just giving the Court fair warning as to
3 where I'm going to go.

4 THE COURT: I believe that that's an objection based
5 on Judge Eifert's ruling and based on prior rulings. And I
6 want to hear your response because I am not going to let you
7 guys --

8 MR. ADAMS: All I was going to do was cover what was
9 on my slide, that they placed 550 Obtryx slings and they had a
10 good experience on it. I don't see what their personal
11 experience has to do with opening the door to lawsuits.

12 MR. MONSOUR: Here's the problem. These doctors say,
13 "Well, I've got -- I don't have any problems." Well, we've
14 got some 20 plaintiffs. Those 20 plaintiffs will tell you
15 otherwise. And, so, he's talking about basically -- they're
16 proffering information which might not be accurate.

17 MR. ADAMS: Well, Your Honor, I used this in my
18 opening statement. I mean, it's pretty innocuous they
19 implanted 550 slings and they all agreed they had low
20 complication rates and they had a good experience with the
21 product. Otherwise, they wouldn't have used it.

22 THE COURT: I'm going to allow you to ask the
23 question. If that's an objection, I overrule it.

24 MR. ADAMS: Okay.

25 THE COURT: Go ahead.

Rosenzweig - Cross - Monsour

1 (Sidebar concluded.)

2 BY MR. ADAMS:

3 Q. Sir, let's go back to where we were. We first
4 talked about Cholhan and then we were talking about the
5 three doctors in West Virginia. You've agreed with me
6 that they collectively implanted somewhere in the
7 vicinity of 500 to 700 Obtryx; correct?

8 A. That is correct.

9 Q. And according to all of them, they had low complication
10 rates; correct?

11 A. That is what they state, yes.

12 Q. And those doctors believe that the Obtryx is -- one of
13 them referred to it as the gold standard. The others referred
14 to it as the standard of care to treat stress urinary
15 incontinence; correct?

16 A. That is what they said.

17 Q. And by low complication rates, they were saying that they
18 were 90 to 95 percent --

19 MR. MONSOUR: Your Honor, objection. This is
20 improper use of deposition testimony. Now we're just
21 bolstering. We are reading doctors', other -- we are
22 summarizing other doctors' testimony that have not or might
23 not testify. And we don't know what's going to come in. And
24 he's basically just using bits and pieces of depositions.
25 This is completely improper. He's cross-examined him with

—Rosenzweig - Cross - Monsour—

1 other doctors' depositions.

2 MR. ADAMS: Well, Your Honor, he reviewed my slides,
3 so he's entitled to say whether he disagrees with them, which
4 he hasn't done. He's reviewed and relied upon the deposition
5 of Dr. Lassere for his opinions.

6 THE COURT: He certainly can testify to any
7 deposition testimony that is the basis of his opinion. Mr.
8 Monsour is correct, however, unless it is used as a basis of
9 an opinion, his reading or repeating deposition testimony is
10 not appropriate.

11 MR. ADAMS: Okay.

12 BY MR. ADAMS:

13 Q. Sir, you would agree with me, to wrap this up, you
14 have no basis to dispute or criticize these three
15 doctors' clinical experience as described by them.
16 Fair?

17 A. I have no basis to dispute that.

18 Q. You have -- when you were describing the transobturator
19 process, how that, how the Obtryx is actually placed within a
20 woman, you were talking about various nerves, the pudendal
21 nerve and the obturator nerve; correct?

22 A. That is correct.

23 Q. And it's undisputed that Ms. Blankenship does not have an
24 injury to either her pudendal nerve or her obturator nerve;
25 correct?

Rosenzweig - Cross - Monsour

1 A. A direct injury?

2 Q. Yes.

3 A. No. Irritation, possibly.

4 Q. All right. You, you would agree with me that there are
5 nerve studies that can be done to determine whether a nerve
6 like the pudendal nerve is damaged; correct?

7 A. Damaged, yes; irritated, no.

8 Q. All right. There's actually neurologists that specialize
9 in that area; correct?

10 A. That is correct.

11 Q. And you'll agree with me that Ms. Blankenship has not
12 been referred by any of her doctors to a neurologist to
13 determine whether there is any objective findings of nerve
14 damage; correct?

15 A. That is correct.

16 Q. You have talked about the risk of erosion. Do you recall
17 that?

18 A. The risk of erosion in what --

19 Q. Let me back up. That was a poor question. When you were
20 talking about dangers associated with polypropylene mesh, I
21 believe that you talked about the risk of erosion and
22 extrusion; correct?

23 A. That is correct.

24 Q. And you'll agree with me that Ms. Blankenship has never
25 had an erosion or an extrusion; correct?

—Rosenzweig - Cross - Monsour—

1 A. She has not been diagnosed with it, yes.

2 Q. And you have talked about that this mesh that is within
3 her body is going to continue to degrade and shrink and
4 contract; correct?

5 A. That is correct.

6 Q. Now, does -- well, strike that.

7 MR. ADAMS: Might I approach, Your Honor?

8 THE COURT: Yes, sir.

9 (The following occurred at sidebar.)

10 MR. ADAMS: Okay. What I would -- I was in an area
11 that I felt like I needed to ask you before I asked the
12 question.

13 THE COURT: Uh-huh.

14 MR. ADAMS: Here's the issue. As you know, Judge
15 Goodwin said we cannot specifically mention the Lynx. Okay.
16 So, what happened was this woman had her Obtryx cut and then,
17 you know, whatever happened, happened.

18 She eventually goes ---she eventually went to another
19 doctor who implanted another sling. That happens to be the
20 Lynx. I am not going to mention that it is a Boston
21 Scientific product, but I believe that I'm entitled to go into
22 the fact that she has had additional mesh put in her body
23 which he's agreed is the same type -- he says it's all
24 defective.

25 So, she's had additional mesh that he believes is all

—Rosenzweig - Cross - Monsour—

1 defective that was implanted in her body after the Obtryx.

2 And there's no way he can say whether any of the damage that
3 she has is a result from this mesh or that mesh.

4 THE COURT: All right.

5 MR. MONSOUR: That's incredibly far from the truth.
6 And I was asking my questions -- you remember I was phrasing
7 it with the Obtryx sling. The pain goes through the obturator
8 and he described it very accurately. He stayed away from the
9 Lynx. Judge Goodwin has already been very clear in his
10 ruling. Lynx is out. It's not to come in.

11 MR. ADAMS: He said I can mention it's a Lynx. I
12 can't mention it's a Boston Scientific product. I'm not going
13 to do it. I'm just going to say she had additional mesh
14 implanted in the same way.

15 THE COURT: I think that it is in his report, if I
16 remember correctly, gentlemen, when he, --

17 MR. ADAMS: It is.

18 THE COURT: -- when he talks about Ms. Blankenship,
19 about the implantation of the second sling. I believe that
20 you should be able to inquire of him on that given the
21 opinions that he's asked.

22 But given the Judge's rulings, I think that you
23 should be precluded from getting into it being the Lynx. If
24 you want an objection and exception on the record, I'll
25 certainly preserve that for you.

—Rosenzweig - Cross - Monsour—

1 MR. MONSOUR: The only point that I would make, Your
2 Honor, is this report was filed and then the motions *in limine*
3 went through and Judge Goodwin was very clear. This, these
4 additional products we're not allowed to go into just like --
5 just like every time I want to stand up and say, "You guys
6 have had your Pinnacle product pulled from the market," and
7 that's transvaginal mesh. It's the same, it's the same thing.
8 They're trying to bring in other products. He's trying to
9 open the door to other things. That's going to be bad for
10 this case.

11 THE COURT: He's not going to bring in the name of
12 the product. But this is a specific causation expert. He
13 should be able to explore with that expert the procedures that
14 Ms. Blankenship has had. But I am going to prohibit you,
15 consistent with the judge's rulings, from going into the fact
16 that it's Lynx or the type of sling.

17 MR. ADAMS: It is a mid-urethral sling and that's all
18 I'll say it is. I'll not say the brand.

19 THE COURT: Do not bring up anything outside of that,
20 counsel. I'm going to preserve an objection and exception for
21 the plaintiff. But given that this is a specific causation
22 witness, I find that it is appropriate for him to be able to
23 cover with this witness the procedures that Ms. Blankenship
24 has gone through.

25 MR. MONSOUR: I would request that he be, he be

—Rosenzweig - Cross - Monsour—

1 required to refer to it as a retropubic sling rather than try
2 and confuse it with another transobturator sling.

3 THE COURT: Do you have an objection?

4 MR. ADAMS: I was just going to say it's a
5 mid-urethral sling.

6 MR. MONSOUR: That's too general and prejudicial.

7 THE COURT: I don't know, quite frankly, that it is
8 prejudicial, but I think that you should refer to it
9 specifically as what it is.

10 MR. ADAMS: As a retropubic, which is a class of
11 mid-urethral sling.

12 THE COURT: That's fine.

13 MR. ADAMS: Okay.

14 (Sidebar concluded.)

15 BY MR. ADAMS:

16 Q. Now, sir, Dr. Rosenzweig, you talked about how
17 after Ms. Blankenship developed some problems she went
18 to see Dr. Lassere. Do you recall that?

19 A. That is correct.

20 Q. And Dr. Lassere then tried to resolve her voiding
21 dysfunction by a procedure where he actually cut the area
22 where the mesh was; correct?

23 A. That is correct.

24 Q. And you'll agree with me that Dr. Lassere -- and you've
25 read his deposition and you're relying upon that. Dr. Lassere

—Rosenzweig - Cross - Monsour—

1 has testified that he could not confirm whether there was any
2 mesh located in that area; correct?

3 A. That is correct. In his operative report, as we read
4 earlier, he said he possibly removed mesh.

5 Q. Okay. And, so, we know that in our timeline she has the
6 Obtryx placed -- and you're free to look at your notes. She
7 has the Obtryx placed on April 8th of 2009; correct?

8 A. That is correct.

9 Q. She has -- according to the records, she had her first
10 report of voiding dysfunction on January 11th of 2011;
11 correct?

12 A. That is correct.

13 Q. So, she went a year and several months of not having any
14 problems with the Obtryx; correct?

15 A. That is correct.

16 Q. And then she has a report -- strike that. Dr. Lassere
17 attempts to revise the Obtryx by doing the cut; correct?

18 A. That is correct.

19 Q. And then after that, Ms. Blankenship develops problems
20 with -- sometime after he cuts the sling, the Obtryx, she
21 develops additional stress urinary incontinence; correct?

22 A. That is correct.

23 Q. And, in fact, you know that Dr. Lassere told her that,
24 "If I do this procedure where I release the Obtryx, then
25 there's a high probability that your stress urinary

—Rosenzweig - Cross - Monsour—

1 incontinence is going to come back." Correct?

2 A. Well, the probability that's quoted in the literature is
3 about 10 to 20 percent.

4 Q. Okay. And, so, her SUI returned; correct?

5 A. That is correct.

6 Q. And just so we're clear, he made his cut on July 11th,
7 2012; correct?

8 A. That is correct.

9 Q. And then the SUI returns after that; correct?

10 A. That is correct.

11 Q. Now, after she was treated by Dr. Lassere as a result of
12 her SUI problems, she was treated by another fine doctor in
13 West Virginia; correct?

14 A. That is correct.

15 Q. And she then went to see Dr. Capelle; correct?

16 A. Yes.

17 Q. And you'll agree with me that she is a very well
18 qualified doctor in this area; correct?

19 A. That is correct.

20 Q. You have no criticisms of the care that she provided;
21 correct?

22 A. That is correct.

23 Q. She, like Dr. Lassere, and all the other doctors, would
24 be keeping up on the scientific literature about the dangers
25 associated with polypropylene slings; correct?

—Rosenzweig - Cross - Monsour—

1 A. That is correct.

2 Q. And when we talk about polypropylene slings or
3 mid-urethral slings, we've already established that in this
4 category there's retropubic; correct?

5 A. That is correct.

6 Q. And that includes the TVT; correct?

7 A. That is correct.

8 Q. The Advantage; correct?

9 A. That is correct.

10 Q. And in the category of transobturator slings is the
11 Obtryx; correct?

12 A. That is correct.

13 Q. And all those devices are defective, according to our
14 earlier discussion, according to you; correct?

15 A. That is correct.

16 Q. And, so, when we go back to our timeline, after the sling
17 was cut and Ms. Blankenship developed SUI again, she was
18 treated by Dr. Capelle; right?

19 A. That is correct.

20 Q. And at that point in time, the SUI problems progressed
21 and they got worse; correct?

22 A. That is correct.

23 Q. And, so, she actually got back to the point that led her
24 to the Obtryx where she decided, "I don't want to live this
25 way with the urinary problems, the pads and things like that."

Rosenzweig - Cross - Monsour

1 Correct?

2 A. That is correct.

3 Q. And then she, in consultation with Dr. Capelle, talked
4 about having yet another surgery involving the implant of
5 another polypropylene mid-urethral sling; correct?

6 A. That is correct.

7 Q. And, in fact, that mid-urethral sling was placed in Ms.
8 Blankenship on March 18th of 2013; correct?

9 A. That is correct.

10 Q. And that device is in the classification of retropubic
11 and transobturator. It was a retropubic sling; correct?

12 A. That is correct.

13 Q. So, I'm going to write "MUS paren RP placed." And our
14 date was March 18th of 2013. And let me show you this,
15 Doctor, because my writing is a little messy. I wrote "MUS
16 retropubic polypropylene sling placed March 18th, 2013."
17 Correct?

18 A. Yes, sir.

19 Q. You agree with that; correct?

20 A. That is correct.

21 Q. And you talk about how long-term this mesh is going to
22 shrink and it's going to degrade and it's going to contract;
23 correct?

24 A. That is correct.

25 Q. Well, the same is true of this other mesh that's inside

—Rosenzweig - Cross - Monsour—

1 of her body now; correct?

2 A. That is correct.

3 Q. And speaking of that, now, you're aware of the fact from
4 reading the deposition of Ms. Blankenship that some time in
5 around 2011 she first concluded that her problems have to be a
6 result of the Obtryx sling because she saw some ads about
7 problems with slings on the TV; correct?

8 A. That is correct.

9 Q. And I don't know the -- I don't recall the exact date,
10 but we've agreed that was sometime in 2011; correct?

11 A. I, I also don't remember the exact date, but I will take
12 your word for it.

13 Q. All right. I'm going to write down "2011 ad." And I'll
14 put a little squibble up there. That means approximately 2011
15 ads; correct?

16 A. That is correct.

17 Q. And then I'll put "Slings the problem" and a "B" for
18 Blankenship. Okay?

19 A. Okay.

20 Q. All right. And, so, even though after, in her belief,
21 she concluded that the Obtryx had to be the cause of her
22 problems, you would agree with me that she then consulted with
23 Dr. Capelle sometime, a year and a half to two years later in
24 2013 and then agreed to the placement of a retropubic sling;
25 correct?

—Rosenzweig - Cross - Monsour—

1 A. Yes.

2 Q. And the mesh used in that retropubic sling, would you
3 agree with me, is very equivalent to the Obtryx mesh; correct?

4 A. That is correct.

5 Q. All right. It's a different approach, but it's the same
6 mesh; correct?

7 A. That is correct.

8 Q. And, so, long-term would you agree with me that to the
9 extent this mesh shrinks, it degrades, it erodes, you're not
10 going to be able to say whether it's due to the mesh from the
11 Obtryx or the mesh that she consented to receive after seeing
12 the advertisements about problems with mesh; correct?

13 A. Are you talking about her current symptom of levator
14 spasm?

15 Q. No. I'm talking about her future problems that you were
16 addressing.

17 A. The future problems?

18 Q. Yes.

19 A. That is correct.

20 Q. All right. And I mean the future problems that you
21 talked about, long-term pain and issues with the mesh
22 degrading; correct?

23 A. That is correct.

24 Q. Bear with me, Doctor. I think -- and ladies and
25 gentlemen. I'm close.

—Rosenzweig - Cross - Monsour—

1 (Pause)

2 BY MR. ADAMS:

3 Q. Oh, I just want to talk briefly about pubovaginal
4 slings. You did -- you had talked about -- you do a
5 procedure with pubovaginal slings where you use
6 Gore-Tex; correct?

7 A. I used to use Gore-Tex. I don't use Gore-Tex anymore.

8 Q. And for what period of time did you use Gore-Tex?

9 A. From about 1989 until the early '90s.

10 Q. Okay. And Gore-Tex -- you'll agree with me that there's
11 never been any type of -- you're aware that there was no
12 randomized clinical trials on Gore-Tex prior to the time that
13 you used it; correct?

14 A. That is correct.

15 Q. All right. And we're going to talk about these RCTs.
16 I'll put "not on Gore-Tex used by Dr. R."

17 A. Correct. But, sir, when I was using Gore-Tex, it was
18 under an experimental protocol. So, patients knew that we
19 were testing this product out, and we ultimately wrote a paper
20 about it.

21 Q. All right. And the TVT-O that you used and, during the
22 period of time from '04 to '07 that we've talked about, do you
23 recall that?

24 A. Yes.

25 Q. You were aware of the fact that there were no randomized

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1 clinical trials done on that product prior to the time that it
2 was put out on the market; correct?

3 A. That is correct.

4 Q. And you knew that from your own personal experience
5 because you keep up on products; correct?

6 A. Well, I had met with the inventor of the TVT Obturator
7 and we discussed his experience and literature that he
8 published on it.

9 Q. All right. But the fact that there was no RCT on the
10 TVT-O did not prevent you from relying upon your own clinical
11 experience and then implanting it in 40 to 50 women; correct?

12 A. That is correct.

13 Q. And when you were talking with the inventor about that
14 and he told you that -- well, let's talk about that. When did
15 the inventor tell you there was no RCT on the TVT-O?

16 A. Well, there was -- when the TVT Obturator was launched,
17 there were, there was a cohort study of, if I remember
18 correctly, 120, 130 patients.

19 Q. All right. After the launch; correct?

20 A. That was around the time of the launch.

21 Q. All right. And let's talk about shrinkage and
22 contracture briefly. You had mentioned that there is an
23 article concerning -- and the name of the article was Wang, I
24 think, A.C. Wang that you referenced?

25 A. That is correct.

—Rosenzweig - Cross - Monsour—

1 Q. And are you aware of the studies that have been done by
2 Dr. Dietz on the issue of shrinkage of polypropylene mesh that
3 is used in the female pelvis?

4 A. Well, actually the study by Wang is on degradation.

5 Q. Okay. Well, let's talk about shrinkage and contracture.
6 Are you aware of the studies done by Dietz on the issue of
7 whether polypropylene mesh shrinks or contracts inside the
8 female pelvis?

9 A. That is correct.

10 Q. All right. So, you are aware of that?

11 A. Yes.

12 Q. And you're aware that Dr. Dietz in an article in 2003
13 entitled "Does Tension-Free Vaginal Tape Stay Put --" let me
14 strike that. Dr. Dietz in an article dated 2003 entitled
15 "Does the Tension-Free Vaginal Tape Stay Where it is Put"
16 concluded that there is no evidence of shrinkage or mesh
17 contracture; correct?

18 A. That was his conclusion which goes against a very large
19 body of literature that shows that another gentleman, Dr.
20 Letouzey, followed up mesh for eight years and found --

21 Q. Mr. Monsour can ask you about Letouzey.

22 MR. MONSOUR: Objection.

23 THE COURT: That objection is sustained. I want him
24 to be able to give a complete answer as I've previously ruled.

25 Finish your answer, please.

—Rosenzweig - Cross - Monsour—

1 THE WITNESS: Dr. Letouzey's study showed that after
2 eight years, there was 85 percent mesh contracture, and that
3 this continued from year one all the way up to year eight.

4 BY MR. ADAMS:

5 Q. Okay. And the Dietz article that we were talking
6 about, I'm not going to take the jury's time to go
7 through that, but you will recognize that that article
8 was published in a scientific journal; correct?

9 A. That is correct.

10 Q. And not only did Dietz, did Dietz publish that article in
11 2003, but then he later published an article in the *American*
12 *Journal of Obstetrics and Gynecology*. That's the green
13 journal; correct?

14 A. That's the gray journal.

15 THE COURT: Is there an objection, counsel?

16 MR. MONSOUR: Yes. Can he be provided -- he's being
17 asked pretty extensive questions. Can he be provided a copy
18 of that study as can I?

19 MR. ADAMS: I will.

20 BY MR. ADAMS:

21 Q. Let me ask you if you're familiar with the study
22 first. Are you familiar with Dr. Dietz's later article
23 that appeared in the gray journal in February of 2011?

24 A. That is correct.

25 Q. Okay. Well, --

—Rosenzweig - Cross - Monsour—

1 THE COURT: Provide the copy then, please, counsel.

2 MR. ADAMS: Certainly.

3 BY MR. ADAMS:

4 Q. Here's Exhibit 1306. And I've got a copy for Mr.
5 Monsour. Briefly, this article is on the issue of mesh
6 contraction; correct?

7 A. That is correct.

8 Q. It says "Mesh Contraction, Myth or Reality." Correct?

9 A. That is correct.

10 Q. And what he did is he examined mesh and did a study on it
11 on over -- I'm sorry. There were 40 women assigned to the
12 study; correct?

13 A. That is correct.

14 Q. And, "Over an observational period of almost 60-woman
15 years, we found no evidence of mesh contraction." Correct?

16 A. That is based on ultrasound, yes.

17 Q. And, so, you'll agree with me that Dr. Dietz, as
18 published in this scientific article that was peer-reviewed,
19 concluded that he didn't observe mesh contraction or shrinkage
20 in almost 60-woman years; correct?

21 A. That is correct.

22 Q. These -- I'd refer to the AUGS statement. And you know
23 from reviewing my opening statement that I talked about that
24 and we had -- the jury's already heard about that; correct?

25 A. That is correct.

—Rosenzweig - Cross - Monsour—

1 Q. But you're aware of the fact that not only AUGS but
2 several other major groups of physicians who practice in the
3 area of urology and urogynecology have issued the same or
4 similar statements; correct?

5 A. Including the European Association of Urology and the
6 American Urologic Association.

7 Q. Very good. And you're right. So, the AUA, the IUGH, and
8 the European society; correct?

9 A. European Association of Urology, yes.

10 Q. Okay. Now, with respect to the Cholhan study, we've
11 already talked about the Cholhan study a little bit. And
12 Cholhan was an article and we've established that there
13 were -- by the way, Mr. Monsour referred to Cholhan as a
14 Boston Scientific study. Do you recall that?

15 A. That is correct.

16 Q. And you're aware that that study was actually performed
17 by outside researchers who are practicing physicians in
18 Canada; correct?

19 A. That is correct.

20 Q. And, so, it wasn't Boston Scientific people that were
21 actually doing the study; correct?

22 A. No. It was funded by Boston Scientific.

23 Q. Right. And on the article it says it's funded by a grant
24 from Boston Scientific; right?

25 A. That is correct.

—Rosenzweig - Cross - Monsour—

1 Q. And you're aware that in the -- it's common for studies
2 on medical devices for companies to actually issue a grant to
3 independent doctors who can do their own research; correct?

4 A. That is correct.

5 Q. And one of the reasons that companies do that is that
6 if -- well, when they give that money to independent doctors,
7 it's to fund the research. But Boston Scientific doesn't have
8 any control over the research; correct?

9 A. We would hope so.

10 Q. Right. Then that's the way the grant process works;
11 correct?

12 A. We would hope so.

13 Q. Okay. And you're not aware of any kind of monkey
14 business going on with respect to the Cholhan or any of the
15 other studies funded by Boston Scientific; correct?

16 A. Not that I'm aware of.

17 Q. All right. And Cholhan involved 25 Obtryx devices;
18 correct?

19 A. That is correct.

20 Q. And Mr. Monsour brought out that, well, there was a
21 24 percent rate of dyspareunia. Do you recall that?

22 A. Yes.

23 Q. And, so, out of the 25 women who were studied, there was
24 a 24 percent rate of dyspareunia. But how many women did that
25 actually account? How many exact numbers?

—Rosenzweig - Cross - Monsour—

1 A. A quarter of 25 would be around six.

2 Q. Well, actually the article says much lower. Do you have
3 it up there? Not much lower, but I think it was four.

4 A. It was four out of 17 because that was the number of
5 patients that were still having -- that were having
6 intercourse at the time. If you're not having intercourse,
7 it's difficult to have pain with intercourse.

8 Q. Okay. So, the number was actually four; correct?

9 A. Out of 17, yes.

10 Q. All right. And I'll put "24 paren 17." Correct?

11 A. No, that's the -- it was four out of 17.

12 Q. You're right. And I should have done this. I'll put "4
13 over 17." Fair?

14 A. That's fair.

15 Q. Okay. And, now, those doctors in Canada that are listed
16 on the Cholhan report, would it surprise you to learn that
17 those doctors actually still use and implant --

18 MR. MONSOUR: Objection. Your Honor, there's no
19 foundation for this. Are they going to testify?

20 THE COURT: You didn't get your question out totally.
21 I think that I know what the question is, counsel. I will let
22 you respond to the objection if you want.

23 MR. ADAMS: I do. Well, I better approach. I don't
24 want to say something that --

25 THE COURT: All right.

—Rosenzweig - Cross - Monsour—

1 (The following occurred at sidebar.)

2 MR. ADAMS: These doctors continue to use the Obtryx
3 device. That's what -- I'm going to ask him whether he's
4 aware of the fact that the doctors in the Cholhan study
5 continue to use the Obtryx device.

6 MR. MONSOUR: It's an improper question. He knows
7 the answer. He's just throwing it out there. He's going to
8 throw a skunk in the jury box and I can't get the smell out.

9 MR. ADAMS: I have a good faith basis for asking the
10 question.

11 MR. MONSOUR: But he has no evidence to support that
12 basis.

13 MR. ADAMS: I have a woman from Boston Scientific who
14 was involved with the study who knows that they still use it.

15 THE COURT: Then we should call her as a witness so
16 she can be subject to cross-examination, Mr. Adams. When we
17 are -- well, I'm going to sustain the objection --

18 MR. ADAMS: Fair enough.

19 THE COURT: -- to the leading question regarding
20 their continued use. I have no reason to believe that this
21 expert used it in any way. And, therefore, I find that it is
22 getting evidence in before the jury without an opportunity for
23 the plaintiff to cross-examine.

24 MR. ADAMS: Fair enough.

25 THE COURT: I preserve the defendant's objection and

—Rosenzweig - Cross - Monsour—

1 exception.

2 MR. ADAMS: And I did want you to know that the
3 reason why I approached is I didn't want to say that in front
4 of the jury until you ruled on it.

5 THE COURT: That's fine. I appreciate that.

6 MR. ADAMS: Okay.

7 (Sidebar concluded.)

8 BY MR. ADAMS:

9 Q. All right. We were talking briefly about Cholhan.
10 And I misspoke, Doctor. I need to clarify that. The
11 Cholhan actually involved doctors located in New York.
12 Do you recall that?

13 A. Yes. The Ross study was actually in Concord.

14 Q. You're right, and I mixed that up. Ross is in Canada.
15 Cholhan was in New York. Correct?

16 A. That is correct.

17 Q. And, now, you have talked about Cholhan -- that Cholhan
18 talked about the issue about banding; correct?

19 A. That is correct.

20 Q. And you have seen the issue of banding occur in other
21 mid-urethral slings; correct?

22 A. That is correct.

23 Q. And you'll agree with me that 89 percent of the Obtryx
24 group in the Cholhan study did not experience any type of
25 deterioration in their post-operative sexual function;

Rosenzweig - Cross - Monsour

1 correct?

2 A. Of the ones that were having intercourse, 75 percent did
3 not have dyspareunia.

4 Q. Okay. And the article also talks about -- when it
5 discusses the complications, it says most of these
6 complications are transient and reversible and, thus, do not
7 have significant long-term repercussions; correct?

8 A. And where are you looking at?

9 Q. That's in the Cholhan study.

10 A. What page?

11 Q. It is on -- bear with me, Doctor. It's on another copy.

12 A. Because we need to know what kind of complications he's
13 talking about. If he's talking about the patient had some
14 immediate post-operative pain, that would be different from
15 someone that has life-changing dyspareunia.

16 Q. I'm sorry, Doctor. I found it. I had the wrong copy.
17 This is on the last page underneath "Conclusions." And this
18 is in the right-hand column up towards the top. Do you see
19 that?

20 A. Yes.

21 Q. And it says, "Increased implementation of TO slings has
22 yielded increasing reports of complications. Most of these
23 complications are transient and reversible and, thus, do not
24 have significant long-term repercussions."

25 Did I read that correctly?

—Rosenzweig - Cross - Monsour—

1 A. That is correct.

2 Q. All right. And with respect to the Ross study, now, the
3 Ross study -- the conclusion of the Ross study was that the
4 authors would recommend the use of the Advantage over the
5 Obtryx; correct?

6 A. That is correct.

7 Q. And the Ross study was done in 2009; correct?

8 A. It would be helpful if I had a copy of it so that I could
9 follow along with you.

10 Q. Certainly. Let me give you one. And this is Defendant's
11 Exhibit 1505.

12 A. Thank you, sir.

13 Q. And that's the same study that we talked about with Mr.
14 Monsour; correct?

15 A. That is correct.

16 Q. And this study was done in 2009; correct?

17 A. It was published in 2009.

18 Q. Right. And it was described as level one evidence;
19 correct?

20 A. That is correct.

21 Q. Because it's an RCT; correct?

22 A. A randomized controlled trial, yes.

23 Q. And there has been another RCT done on the Obtryx that is
24 very recent; correct?

25 A. That is correct.

—Rosenzweig - Cross - Monsour—

1 Q. All right. And at the time of your deposition, isn't it
2 true that you had researched the articles available on the
3 Obtryx and the only two articles that you found were Ross and
4 Cholhan; correct?

5 A. No, I had several others, the Smith article and a few of
6 the abstracts.

7 Q. Okay.

8 A. Sometimes it's more difficult to get abstracts. They're
9 not published in the peer-reviewed journal. They're just
10 somebody that's presented at a meeting so that people can get
11 feedback on the research. So, it hasn't gone through a
12 peer-review process to be presented as an abstract.

13 Q. Now -- and -- but in your material that you reviewed and
14 you relied upon for your opinions in this case, the only two
15 articles on the Obtryx were Cholhan and Ross; correct?

16 A. In the Rule 26 report, yes.

17 Q. Right. And in the Rule 26 report you must list all the
18 studies or documents that you have reviewed or are relying
19 upon; correct?

20 A. For the opinions, yes.

21 Q. All right. And, so, you didn't review -- well, strike
22 that. You didn't list for your opinions documents that you
23 may have considered that reach opposite conclusions or
24 different conclusions than Ross and Cholhan on the Obtryx;
25 correct?

—Rosenzweig - Cross - Monsour—

1 A. Those were the two that I used in my report, yes.

2 Q. Right. But you did not list on your report any of the
3 other studies done on the Obtryx; correct?

4 A. At that time, those were the two that were in
5 peer-reviewed literature.

6 Q. Okay. And on the Ross study, if we could pull that up
7 just briefly. And this is 1505.

8 MR. ADAMS: And, Your Honor, may I publish it? I
9 believe Mr. Monsour already established this is a learned
10 treatise and cross-examined him on it.

11 THE COURT: Yes, sir.

12 MR. ADAMS: I'm sorry, did a direct exam with him on
13 it.

14 THE COURT: Yes, sir.

15 MR. ADAMS: Thank you, Your Honor.

16 BY MR. ADAMS:

17 Q. If you would put up 1505 and if we could real
18 quickly go to this article. The jury's already seen
19 this. And if we will turn on Page 1291, Jim, just
20 briefly and blow up the highlighted section.

21 Now, part of this article was the doctors making
22 observations about the existence of palpable mesh; correct?

23 A. That is correct.

24 Q. And what palpable mesh means is that when you push on an
25 area, you can feel it; correct?

—Rosenzweig - Cross - Monsour—

1 A. That is correct.

2 Q. And, so, for like a hernia surgery, you can push on an
3 area for somebody that's had hernia surgery using mesh and you
4 can actually feel that there is something there to bolster the
5 tissue; correct?

6 A. That is correct. And, in fact, there's a, a medical
7 condition called pain in the inguinal area from inguinal mesh.

8 Q. Right. And you'll agree with me that not everybody that
9 gets a hernia operation with mesh experiences any type of
10 problem; correct?

11 A. Actually, the amount of patients that have hernia surgery
12 that have problems is, is not insignificant.

13 Q. Okay. Now, in this article one of the things that they
14 reported was actually the interviews and the expectation of
15 the women who went under the procedure of either having an
16 Obtryx used or an Advantage used; correct?

17 A. That is correct.

18 Q. And it says in this column, right before the discussion
19 it says, "The majority of women reported that the surgery met
20 their expectations (78) --" and 78 is the number of women
21 actually; correct?

22 A. That is correct.

23 Q. And the percentage of women in the Obtryx group was
24 90.7 percent; correct?

25 A. Well, that was the number of women that completed the

—Rosenzweig - Cross - Monsour—

1 one-year evaluation. So, these --

2 Q. Fair enough.

3 A. This is the information that they're obtaining at the end
4 of one year.

5 Q. Fair enough. And when you were talking with Mr. Monsour,
6 you were relying upon the same one-year information; correct?

7 A. That is correct.

8 Q. Right. And at one year 90.7 percent of the women in the
9 Obtryx transobturator group said that the surgery met their
10 expectations; correct?

11 A. That is correct.

12 Q. And as compared with 84 percent in the TVT group;
13 correct?

14 A. That is correct.

15 Q. And it said they would recommend the surgery to someone
16 else with similar symptoms. 95 percent of the ladies in the
17 Obtryx group said they'd recommend it to somebody else
18 compared with 88 percent or, I'm sorry, 92 percent in the TVT
19 or the Advantage group; correct?

20 A. That's what the paper states, yes.

21 Q. Right. So, what the paper states is that according to
22 the actual women who were involved in the study, those women
23 prefer the results of the Obtryx over the results of the TVT;
24 correct?

25 A. At one year, yes.

—Rosenzweig - Cross - Monsour—

1 Q. Doctor, I've got one last study to discuss with you.
2 Actually, I lied. Two last studies and I'll be quick about
3 it. The most recent study that was done on the Obtryx, have
4 you read that prior to coming in here to testify?

5 A. That is correct.

6 Q. All right. And that is the Tarcan study; correct?

7 A. That is correct.

8 Q. And Tarcan, like the Ross study, is a randomized clinical
9 trial; correct?

10 A. That is correct.

11 Q. And the Tarcan study was published just recently in 2014;
12 correct?

13 A. That is correct.

14 Q. The Ross study we've established was published in
15 December of 2009; correct?

16 A. That is correct.

17 Q. And, so, now almost five years later we have another RCT
18 from Tarcan; correct?

19 A. That is correct.

20 Q. And the Tarcan study was published in the *International*
21 *Urology Journal* and it's, it's designated as *Urology*
22 *International*. You're familiar with that journal; correct?

23 A. Actually, that is a rather obscure urology journal from
24 Italy if I'm correct.

25 Q. Let me hand this to you and I'll give you a better copy.

—Rosenzweig - Cross - Monsour—

1 MR. ADAMS: And I've got a copy for you, Mr. Monsour,
2 a copy of Defendant's Exhibit 1158.

3 MR. MONSOUR: I've got it.

4 MR. ADAMS: Okay.

5 BY MR. ADAMS:

6 Q. And this journal, you're aware of the fact that
7 this is a peer-reviewed journal; correct?

8 A. Again, this is an obscure journal, so I will take your
9 word that it is a peer-reviewed journal.

10 Q. All right. And you recognize papers like this from a
11 peer-reviewed journal as being authoritative, correct, or at
12 least reliable; correct?

13 MR. MONSOUR: Objection.

14 THE COURT: The objection is overruled. I'm going to
15 let him answer if he can.

16 THE WITNESS: I don't know this journal in
17 particular. There are good peer-reviewed journals. There are
18 journals that pretty much accept any article that comes along.
19 So, it's difficult to say. This is not one of the top
20 urology, urogynecology, or OB/GYN journals.

21 Q. Okay. And --

22 THE COURT: Let me interrupt, Mr. Adams.

23 Mr. Monsour, I should have let you state your grounds
24 for your objection. Did I understand it?

25 MR. MONSOUR: I withdraw my objection. He can

—Rosenzweig - Cross - Monsour—

1 proceed.

2 THE COURT: All right. Thank you. Go ahead, please.

3 BY MR. ADAMS:

4 Q. And, sir, before you testified today did you at
5 least review this article?

6 A. Yes, sir.

7 Q. And, so, you've reviewed it in connection with the
8 opinions that you were giving in this case; correct?

9 A. That is correct.

10 Q. And because you wanted to consider all evidence
11 concerning testing or randomized clinical trials done on the
12 Obtryx; correct?

13 A. That is correct.

14 Q. That was part of your work as an expert; correct?

15 A. That is correct.

16 MR. ADAMS: And, Your Honor, on that basis, I move to
17 publish the article because he's reviewed and studied the
18 article as part of his work as an expert.

19 THE COURT: Any objection, counsel?

20 MR. MONSOUR: A limiting objection that Mr. Adams
21 follow any prior motions *in limine* made by either you or Judge
22 Goodwin. I think he knows what they are.

23 THE COURT: I expect both, all parties at all times
24 to follow the prior rulings of the Court, counsel.

25 MR. ADAMS: I do too and I addressed his concern.

—Rosenzweig - Cross - Monsour—

1 THE COURT: All right. Go ahead.

2 MR. ADAMS: Frankly, I didn't know where he was
3 going, but now I do and I appreciate counsel's statement.

4 BY MR. ADAMS:

5 Q. Let's talk about this article really quick.

6 MR. ADAMS: Your Honor, may I put it up on the screen
7 now?

8 THE COURT: Yes, sir.

9 BY MR. ADAMS:

10 Q. It's 1158. Now, this article -- and I realize that
11 you're not familiar with the journal. But it's called
12 "Safety and Effective --" "Safety and Efficacy of
13 Retropubic or Transobturator Mid-Urethral Slings in a
14 Randomized Cohort of Turkish Women." Correct?

15 A. That is correct.

16 Q. And this is a study that was published on April 24 of
17 2014; correct?

18 A. No. That's when it was received by the journal. Then
19 approximately one month later they received the revisions, and
20 then it was published online August 20th, 2014.

21 Q. That's my point. So, it was received on the 24th and
22 then published more recently in August; correct?

23 A. That is correct.

24 Q. And this article, it says at the top in this paragraph
25 that -- underneath "Objective" it says the aim of this study

—Rosenzweig - Cross - Monsour—

1 was to evaluate -- let me slow down. It says, "The aim of
2 this study was to evaluate the safety and efficacy of
3 retropubic or transobturator TO mid-urethral slings in a
4 prospective randomized cohort of Turkish women."

5 Now, the RCT we've established is level one evidence;
6 correct?

7 A. The RCT can be level one evidence. It not only has to be
8 randomized and controlled but, as I talked about before, it
9 has to have a large sample size and it has to have reliable
10 methodology which you'll find in the methodology section.

11 Q. Okay. And this -- it goes on to say that a total of 54
12 women with urodynamic stress urinary incontinence were
13 randomized to undergo either retropubic or transobturator MUS,
14 mid-urethral slings, between August, 2006, and February, 2013,
15 in a tertiary referral center by a single surgeon. Correct?

16 A. That is correct.

17 Q. And I don't think the jury's heard that term "tertiary
18 referral center." What's that mean?

19 A. Well, they actually go on to explain that at the end of
20 the article. They say that they are a referral center for --
21 the reason why it took them seven years to collect 50
22 patients, that's about eight patients a year, was because they
23 get referrals from other doctors.

24 And mostly what they get, as they state on Page 4, is
25 they say that they might have a low number of patients that

—Rosenzweig - Cross - Monsour—

1 are referred to them because they're mostly dealing with
2 complications.

3 So, this is an article about slings. Probably what
4 they're dealing with is mid-urethral sling complications.

5 Q. All right. And it says, "All patients --" we've already
6 read that. Let's go down to the bottom part on the results
7 and real quickly read this, if we could blow up the next
8 portion that's highlighted.

9 It says, "The Advantage retropubic and the Obtryx
10 transobturator mid-urethral sling systems were used for all RP
11 and TO procedures."

12 Did I read that correctly?

13 A. That is correct.

14 Q. And it then says, "27 patients were randomized to each
15 group."

16 Did I read that correctly?

17 A. Yes, you did.

18 Q. And then it says, "The overall objective and subjective
19 cure rates were between 92.6 and 79 percent respectively. The
20 quality of life of all patients significantly increased after
21 the operation compared to their pre-operative," and the next
22 word is "status."

23 Did I read that correctly?

24 A. That is correct.

25 Q. And then under "Conclusion" it says, "Mid-urethral sling

—Rosenzweig - Cross - Monsour—

1 surgery is highly effective and could safely be performed in a
2 cohort of Turkish women with stress urinary incontinence in
3 subspecialty centers by experienced surgeons. There is no
4 significant difference between retropubic or
5 transobturator --" and the transobturator is the Obtryx;
6 right?

7 A. In these 50 patients, yes.

8 Q. "There is no difference between the RP or the TO
9 applications in terms of safety and efficacy."

10 Did I read that correctly?

11 A. That is correct.

12 Q. And you know, sir, that the Obtryx continues to be used
13 by doctors throughout the world; correct?

14 A. Not in Scotland.

15 Q. All right. All the other countries doctors continue to
16 use the Obtryx; correct?

17 A. Australia is actually looking at the, the issue too.

18 Q. Not my question. The Obtryx is being used in those, all
19 those other areas of the world besides Scotland; correct?

20 A. I don't know of other countries that have prohibited the
21 use.

22 Q. Now, --

23 THE COURT: Mr. Adams, I want to give the jury a
24 break. I thought I would get to a stopping point.

25 MR. ADAMS: I'm very close.

—Rosenzweig - Cross - Adams—

1 THE COURT: They've been in the box for two hours.

2 MR. ADAMS: And let's take a break, Your Honor, and
3 I'll organize my thoughts and I'll finish quickly.

4 THE COURT: Ladies and gentlemen of the jury, I'll
5 give you a recess. While you're out, do not discuss the case
6 among yourselves or permit anyone to discuss it with you or in
7 your presence. And please be in your jury lounge at five
8 minutes till the hour.

9 (A recess was taken from 3:33 p.m. to 3:55 p.m.)

10 (The Jury entered the courtroom at 3:55 p.m.)

11 THE COURT: Mr. Adams?

12 MR. ADAMS: Thank you, Your Honor. May it please the
13 Court.

14 THE COURT: Yes, sir.

15 BY MR. ADAMS:

16 Q. Dr. Rosenzweig, I've just got a couple of more points,
17 and then I'll turn it over to Mr. Monsour.

18 This second retropubic sling that was placed on March
19 18th of 2013, it has resolved any complaints that
20 Ms. Blankenship has as a result of stress urinary
21 incontinence, correct?

22 A. That is my understanding, yes.

23 Q. And her current complaints consist of chronic pain and
24 dyspareunia, correct?

25 A. That is correct.

—Rosenzweig - Cross - Adams—

1 Q. And with respect to Dr. Lassere, we talked about him. I
2 wanted to clarify that you know that Dr. Lassere, after using
3 the product, the Obtryx product, he did start using another
4 product as a result of a change in the hospital, correct?

5 A. That's what he testified to.

6 Q. Right. And he agreed that he didn't switch for any
7 reasons of safety or efficacy, correct?

8 A. That's what he testified to.

9 Q. Okay. And then the last issue, on the day when
10 Dr. Lassere examined Ms. Blankenship, prior to doing the
11 procedure, he took a history, correct?

12 A. That is correct.

13 Q. And this is part of Exhibit 14, which is already in
14 evidence.

15 MR. ADAMS: And, Your Honor, may I display this?

16 THE COURT: Yes, sir.

17 MR. ADAMS: Okay.

18 (The document was published to the jury.)

19 BY MR. ADAMS:

20 Q. So pre-procedure, Dr. Lassere, in this record, had
21 examined Ms. Blankenship.

22 MR. ADAMS: And blow it up a little bit higher than
23 that, Jen.

24 BY MR. ADAMS:

25 Q. To clarify, he says, "Patient has also significant

—Rosenzweig - Cross - Adams—

1 problems with urinary incontinence. She has been wearing
2 adult diapers for the past two years for protection," correct?

3 A. That is correct.

4 Q. You and I talked about that earlier, correct?

5 A. That is correct.

6 Q. And, again -- and this is the day that he does the
7 procedure, correct?

8 A. That is correct.

9 Q. And he obviously -- on that day, he also notes that her
10 prior history is that "Patient does have other symptoms of
11 pelvic discomfort, pain with sex, and pain with her menses,
12 which may warrant workup in the future." Did I read that
13 correctly?

14 A. That is correct. And --

15 Q. That exists before the Obtryx, correct?

16 A. That is correct. And she gave that on the day that she
17 had a urinary tract infection.

18 Q. And then when we look at -- under "plan" on the last
19 page, it says -- if you can blow that up -- it says, "Will
20 consider expectant management of her chronic pelvic pain
21 problems and work up as needed." Did I read that correctly?

22 A. That is correct. Expectant management means doing
23 nothing.

24 Q. Okay. And I don't have any other questions for you at
25 this time, and I appreciate your patience, Doctor.

—Rosenzweig - Redirect - Monsour—

1 THE COURT: Redirect, Mr. Monsour.

2 MR. MONSOUR: Thank you, Your Honor.

3 (REDIRECT EXAMINATION OF BRUCE ROSENZWEIG BY MR. MONSOUR:)

4 Q. Are you ready?

5 A. Yes, sir.

6 Q. Okay. There was a lot of things that were discussed with
7 Mr. Adams, so I'm going to -- I want to be organized, but I'll
8 try and address them one by one if I can.

9 The first thing I want to do is I want to talk to you
10 about the last study that was put in front of you, which was
11 the Tarcan study. And the Tarcan study was the Turkish study,
12 and you were shown this by Mr. Adams, and it said, in the
13 Obtryx group, there was a 79 percent success rate. Do you
14 remember that?

15 A. That is correct.

16 (The document was published to the jury.)

17 BY MR. MONSOUR:

18 Q. Now, if you look -- if I look at the front part of the
19 document, it talks about how there was follow-up at 48 months,
20 but if we look -- oh, okay. If you got -- if you will look
21 here on the first page, it talks about a success rate -- and
22 if you can blow that up -- the success rate for the TOT
23 procedure, which was the Obtryx, was 79 percent, correct?

24 A. That is correct.

25 Q. Is that an impressive success rate in your opinion?

—Rosenzweig - Redirect - Monsour—

1 A. No, because that data point was collected at one year.

2 Q. Okay.

3 A. Success rate at one year was 79 percent.

4 Q. Okay. But when you say you have a success rate of 79
5 percent, that means at one year, 21 percent of the procedures
6 failed. That's one in five, correct?

7 A. That means that they are still leaking urine when they
8 cough and sneeze, that is correct.

9 Q. At one year, correct?

10 A. That is correct.

11 Q. How does your Burch procedure stack up to these results
12 found in an obscure Turkish journal?

13 A. It's 90 to 95 percent successful at one year.

14 Q. Okay. Now, let's turn to the second page of the obscure
15 Turkish journal, and if we can look at --

16 MR. ADAMS: Objection, Your Honor. I object to the
17 mischaracterization.

18 THE COURT: The term "obscure"?

19 MR. ADAMS: Yeah.

20 THE COURT: I am going to sustain the objection.

21 Based on the testimony of the witness, the jury can determine
22 what weight to give to it. I don't think you lawyers should
23 add weight to it in the questions.

24 MR. MONSOUR: Okay.

25 BY MR. MONSOUR:

Rosenzweig - Redirect - Monsour

1 Q. Under the "results" section, if we look above, it talks
2 about in the third paragraph, in that paragraph, yes, it says,
3 "Subjective and objective cure rates were evaluated at months
4 1 and 12 after surgery." Is that correct?

5 A. That is correct.

6 Q. Okay. So let's go back to Jeanie Blankenship. If data
7 was collected at one year, the problems that Jeanie
8 Blankenship has would not show up in this Turkish study,
9 correct?

10 A. That is correct.

11 Q. Okay. Now, at the back of the Turkish study, it says, on
12 the last paragraph before conclusions of the Turkish study, it
13 says, "The major limitation of this study is related to the
14 relatively low number of patients recruited over a wide range
15 of time." Do you remember that?

16 A. That is correct.

17 Q. Then it says, "Another" -- down at the bottom, "Another
18 obvious limitation is that our results can only be validated
19 in a short-term follow-up." That's the 12-month data
20 collection point, correct?

21 A. That is correct.

22 Q. Okay. It says, "Also, this study is unable to provide
23 data on the effect of stress urinary incontinence surgery on
24 sexual function or standardized classification of the
25 complications." Correct?

Rosenzweig - Redirect - Monsour

1 A. That is correct. This is not a safety study.

2 Q. Okay. So, and if we go up into the previous paragraph
3 immediately above that, right there, do the bottom half down,
4 if you can.

5 This is the one I want you to focus on. I want you to
6 explain to the jury why this is important. It says, "Since
7 not all synthetic devices are equal, only those meshes that
8 have been tested in carefully controlled clinical trials with
9 adequate safety, efficacy and adverse event data should be
10 used." Is that what it says?

11 A. That's what it says, and that's what I agree with.

12 Q. Okay.

13 A. That we need data to say whether something is safe and
14 effective. These are devices that are going to be implanted
15 in a woman's body for 35 years. We need to know that it's
16 safe and effective longer than one year to be able to draw any
17 conclusions.

18 Q. Okay. Now, if we look at this study, is this study
19 actually saying use this study to show how safe the product
20 is, or what is this study saying?

21 A. Well, this study, first of all, said that it wasn't able
22 to monitor complications such as pain with intercourse or
23 other complications; secondly, they admitted that it is a
24 short-term study; and, third, they go on to say that in order
25 to be able to say whether something is safe and effective, you

—Rosenzweig - Redirect - Monsour—

1 need a longer term study.

2 Q. So they say we need longer term studies that collect
3 safety data, and, by the way, we're not a long-term study and
4 we don't collect safety data; fair enough?

5 A. That is correct.

6 Q. All right. I want to talk with you about the Dietz
7 paper. Now, the Dietz paper sounds impressive. It's a
8 60-year study that shows no shrinkage. So, by my chart, it
9 says, one, two, three, four, five, six, seven, eight, nine,
10 ten, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21 -- let's keep
11 going. That study should come out to probably somewhere
12 around here. That's a pretty long-term study. That's 60
13 years. That is powerful, Doctor. How can you refute the
14 Dietz study that is so powerful, it's 60 years long?

15 A. Well, what they say is, women years. So what they do is
16 they multiply the number of women by the number of years that
17 they were following them to get 60 women years.

18 Q. So let me see if I understand this. On the ELMO, it
19 says -- on the ELMO of the Dietz study, it says, "In
20 conclusion, we have not observed any evidence of mesh
21 shrinkage in 40 women after Perigee mesh implantation followed
22 up for an average of 18 months." Is that what it says?

23 A. That's what it says.

24 Q. So, again, we could stack up 40 different Jeanie
25 Blankenships, and we never even make it to the 21-point

Rosenzweig - Redirect - Monsour

1 symptom mark.

2 MR. ADAMS: Objection, Your Honor, leading.

3 THE COURT: The objection is sustained, inasmuch as
4 there was no question there, period, not even in tone,
5 Mr. Monsour.

6 MR. MONSOUR: Okay.

7 BY MR. MONSOUR:

8 Q. Was the last statement that I made correct?

9 A. That was correct.

10 THE COURT: Well, that is asking him to affirm your
11 testimony and I have not put you under oath, so I won't permit
12 that either, counsel.

13 MR. MONSOUR: All right. I will restate my question,
14 Your Honor.

15 THE COURT: All right.

16 BY MR. MONSOUR:

17 Q. In the Dietz study, the average woman that was looked at
18 was 18 months; is that fair?

19 A. That is correct.

20 Q. And with regard to the -- looking at 18 months, when did
21 Jeanie Blankenship's symptoms first show up?

22 A. Approximately 21 months.

23 Q. So if we had looked at Ms. Blankenship or we were looking
24 at this from a symptoms basis, we probably -- or we might not
25 have even seen that with Jeanie Blankenship, who does have

Rosenzweig - Redirect - Monsour

1 problems. Is that fair?

2 A. That is correct.

3 Q. Okay. Now, you were asked about your use of other
4 synthetic meshes, do you remember that, by Mr. Adams?

5 A. Yes, sir.

6 Q. And they asked you -- or he asked you about your use of
7 TVT, and your use of TVT-O. Is that correct?

8 A. Yes.

9 Q. Now, before -- and he asked you, he said, before J&J
10 marketed those products; did they do a randomized controlled
11 trial on them? Do you remember that question?

12 A. Yes.

13 Q. And your answer to that question was what?

14 A. No.

15 Q. Let me ask it another way. Did J&J, the competitor of
16 Boston Scientific, look at this product or these products in
17 women's vaginas and test them in women's vaginas before they
18 sold the products?

19 A. Yes.

20 Q. For the TVT product, how many women were implanted with a
21 synthetic mesh device before marketing?

22 A. Well, there was a study done by the company that sold the
23 device to Johnson & Johnson called Med Scan, and they had 131
24 patients. Prior to that, the inventor had done a study on a
25 device that he made himself which was with the prototype and

—Rosenzweig - Redirect - Monsour—

1 had somewhere around 60 or 70 patients, if I remember
2 correctly.

3 Q. Okay. All right. With regard to their follow-up product
4 which would have been, like, the first was the TVT, the
5 retropubic. (Indicating.) The second product was the TVT-O,
6 the obturator product. (Indicating.) Did they then later
7 test that product on women before they marketed it? And when
8 I say test it, I mean implant it, transvaginally, as it would
9 be intended after marketing.

10 A. That is correct.

11 Q. And how many women did they look at?

12 A. There was a study by Dr. de Leval that had approximately
13 120 to 130 patients.

14 Q. So if we look at the lowest numbers, we take about 180 on
15 the low end, what is that? 311? On the low end, 311 women
16 were looked at by J&J with these products implanted before
17 marketing, correct?

18 A. Actually, the number is higher. I forgot to mention that
19 there was a study by Dr. Wang that was also accomplished, and
20 I can't remember the number, but it was somewhere around a
21 hundred patients.

22 Q. Okay. So I'll say -- (Indicating.)

23 Now, we heard yesterday during the testimony of Peggy
24 Pence that Boston Scientific looked at 36 rabbits, and that
25 for the second product, they used the same data from the same

—Rosenzweig - Redirect - Monsour—

1 36 rabbits.

2 Can you think of any reason why a company that would be
3 implanting a product in a woman's vagina would perform this
4 step but would not perform the second step before they
5 marketed the product? (Indicating.)

6 A. I could speculate that it might be cheaper to do it in
7 rabbits.

8 Q. Okay.

9 MR. ADAMS: Move to strike the speculation, Your
10 Honor.

11 THE COURT: The objection to the answer as to
12 speculating as to it being cheaper, that objection is
13 sustained. Ladies and gentlemen, I'm going to order it
14 stricken from the record and that it not be a part of your
15 consideration in this case.

16 BY MR. MONSOUR:

17 Q. Now, you mentioned before your testifying experience.
18 You were cross-examined about that, correct?

19 A. That is correct.

20 Q. Do -- of the money that you have been paid in -- for
21 being an expert in transvaginal mesh, has that involved a
22 significant number of women?

23 A. Yes.

24 Q. Give us a ballpark of how many.

25 MR. ADAMS: Objection, Your Honor. May we approach?

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1 THE COURT: Yes, sir.

2 (The following occurred at sidebar.)

3 MR. ADAMS: This is a back-door way of getting in the
4 number of lawsuits, which I don't think he's entitled to get
5 in.

6 MR. MONSOUR: He brought it up, so it sounds like
7 he's made a million dollars working on this case and that's
8 very misleading. I mean, half these people were patients of
9 Bard or J&J. There is a lot of case-specific work with -- his
10 work on Boston Scientific has been relatively minimal. If
11 he's going to cross-examine him about J&J and Bard, I've got
12 to clarify it.

13 MR. ADAMS: He's testified --

14 THE COURT: I'm going to preclude any evidence that
15 gets into other lawsuits consistent with the prior rulings.

16 I believe that portion of his testimony, Mr. Monsour,
17 where he was asked about that litigation with respect to
18 Boston Scientific is not such that the jury necessarily would
19 infer that it is this case. And, again, I do not think that
20 that opens up the door to getting into the other lawsuits and
21 I'm going to preclude it, preserving the plaintiffs' objection
22 and exception.

23 MR. MONSOUR: Can I tell you my next question and ask
24 if it's okay since it might cross the line and I don't want to
25 do that?

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1 THE COURT: Okay.

2 MR. MONSOUR: This case involved more plaintiffs
3 beforehand and on one of the plaintiffs, we sent her medical
4 records to them and he said this is not a case and he told us
5 to drop the case. Can I ask that question?

6 THE COURT: I think because his credibility and his
7 bias is always an issue, you can ask him whether he has ever
8 refused a plaintiff's case if you want to.

9 MR. MONSOUR: Okay, okay. Thank you.

10 THE COURT: If you want to object to that, I will
11 permit you to and preserve it.

12 MR. ADAMS: I do object to it. I mean -- well, if
13 you can stay away from this case.

14 MR. MONSOUR: I will. I will just say generally, not
15 this specific case --

16 THE COURT: I believe that's fair because in
17 cross-examination, there were some questions asked that
18 established bias if the jury decides to interpret it in that
19 way, and so I believe that this is appropriate redirect in the
20 manner that I have instructed it to be asked.

21 MR. MONSOUR: Okay. Thank you.

22 MR. ADAMS: And note my objection and I appreciate
23 the Court's ruling.

24 THE COURT: I preserve the defendant's objection and
25 exception.

—Rosenzweig - Redirect - Monsour—

1 MR. ADAMS: Thank you.

2 (Sidebar concluded.)

3 BY MR. MONSOUR:

4 Q. Without naming the case or giving any -- anything too
5 specific, have we asked you to look at cases before involving
6 plaintiffs with transvaginal mesh where you've said, Doug,
7 there's not a case here?

8 MR. ADAMS: Objection, Your Honor. I don't --
9 well --

10 THE COURT: You don't?

11 MR. ADAMS: Well, my statement is, I don't believe
12 that that was consistent with what the Court said at the
13 bench.

14 THE COURT: I sustain that objection.

15 MR. ADAMS: Yes.

16 MR. MONSOUR: Let me reask the question.

17 (Discussion held off the record between Mr. Adams and
18 Mr. Monsour.)

19 THE COURT: I'm feeling very left out up here.

20 (Laughter.)

21 MR. ADAMS: Your Honor, I was trying to assist him.

22 THE COURT: All right. Go ahead, Mr. Monsour.

23 BY MR. MONSOUR:

24 Q. Let me try again.

25 Is it a fair statement to say that you have refused to

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1 testify on behalf of a plaintiff before?

2 A. That is correct.

3 Q. In other words, every case that is sent to you, you don't
4 agree to be an expert on?

5 A. That is correct.

6 Q. Okay. Now, you were also asked about your testimony in
7 medical malpractice cases. Do you remember that?

8 A. Yes, sir.

9 Q. Is there anything wrong with representing patients?

10 A. No.

11 Q. Do you have any second thoughts about being willing to
12 testify when people are injured?

13 A. No.

14 Q. Do you stay up late at night worried that some of your
15 brethren might get their feelings hurt if you criticize them
16 when they make a mistake?

17 A. I think that that is a concern.

18 Q. But you do it anyway.

19 A. Yes, sir.

20 Q. Now, in these cases, you were looking at the medical --
21 you looked at the medical record in Ms. Blankenship's case,
22 correct?

23 A. That is correct.

24 Q. If you had seen medical error by Dr. Lassere, you would
25 have told me, right?

—Rosenzweig - Redirect - Monsour—

1 A. That is correct.

2 Q. You didn't, you didn't mention anything, did you?

3 A. That is correct.

4 Q. And that's because you could rule it out by the delayed
5 reaction of the sling slowly shrinking over time, right?

6 A. That is correct.

7 Q. If a sling is implanted properly, with the proper
8 tension, and over time it shrinks up, that's not the doctor's
9 fault, is it?

10 A. No.

11 Q. Would it be inappropriate for Boston Scientific to blame
12 Dr. Lassere for the problems of Ms. Blankenship?

13 MR. ADAMS: Objection. One, cumulative. Two, we
14 have already established we're not blaming him.

15 THE COURT: I understand the latter part of your
16 objection. Counsel, I'm going to overrule it and permit the
17 question.

18 MR. MONSOUR: Thank you.

19 BY MR. MONSOUR:

20 Q. Would you answer the question?

21 A. That would be inappropriate.

22 Q. Now, you were asked questions about the directions for
23 use and what Dr. Lassere went over with Ms. Blankenship. Do
24 you remember those questions from Mr. Adams?

25 A. Yes.

—Rosenzweig - Redirect - Monsour—

1 Q. And he asked you, he said, isn't it true that you read
2 from Dr. Lassere's deposition that he went through all the
3 problems with her that are listed in the directions for use;
4 do you remember that?

5 A. Yes.

6 Q. If Dr. Lassere went through all of the problems that are
7 listed in the directions for use and only those problems,
8 would he have gone through lifelong complications?

9 A. No.

10 Q. Would he have gone through shrinkage?

11 A. No.

12 Q. Would he have gone through contraction?

13 A. No.

14 Q. Would he have gone through degradation?

15 A. No.

16 Q. Would he have gone through the fact that the product
17 cannot be removed?

18 A. There is no standardized, reliable, effective way of
19 removing all the mesh in women that have had obturator slings,
20 if it creates a problem.

21 Q. Let's look at the directions for use and let's see what
22 he would have gone through with her.

23 (The document was published to the jury.)

24 MR. MONSOUR: If we can zoom in.

25 BY MR. MONSOUR:

—Rosenzweig - Redirect - Monsour—

1 Q. It notes here, "Tissue responses of the implant could
2 include vaginal extrusion, erosion through the urethra, or
3 other surrounding tissue, migration of the device from the
4 desired location, fistula formation, and inflammation. The
5 occurrence of these responses may require removal of the
6 entire mesh." Did I read that correctly?

7 A. Yes, you did.

8 Q. It seems simple enough. If you've got a problem, just
9 take it out. We put it in in 20 minutes. We'll just take it
10 out. Easy enough, right?

11 A. Actually, no.

12 Q. So when Jeanie Blankenship is meeting with her doctor,
13 he's telling her, hey, if you got one of these problems, we'll
14 just take it all out, right?

15 MR. ADAMS: Objection, Your Honor. This is all
16 leading and counsel's testifying.

17 THE COURT: Counsel, with respect to that question, I
18 am going to sustain the objection. I told you all before, I
19 think it's proper with respect to certain issues to lead an
20 expert. This is not one of those questions.

21 MR. MONSOUR: I will rephrase.

22 THE COURT: All right. I sustain the objection.

23 MR. MONSOUR: Thank you, Your Honor.

24 BY MR. MONSOUR:

25 Q. If Dr. Lassere went through the directions for use, would

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1 he have told her that the mesh could be removed in its
2 entirety?

3 A. Well, that's what's suggested by the instructions for
4 use.

5 Q. Okay. And is there anything in here that talks about the
6 difficulty in removing the mesh?

7 A. No.

8 Q. Let's talk about balancing. So when Jeanie and
9 Dr. Lassere are sitting down and Jeanie's making the decision,
10 let's talk about what can go wrong with me, how is she
11 supposed to make a good decision when she doesn't know about
12 all these problems?

13 A. That would be quite difficult.

14 Q. Now, another thing I want to ask you about is the
15 editorial, the AUGS editorial. I think Mr. Adams likes it, so
16 I want to ask you a question about it.

17 The AUGS editorial, it talks about 99 percent of the
18 doctors that use slings. You started an answer, you didn't
19 get a chance to finish it. Would you tell the ladies and
20 gentlemen of the jury why is the AUGS statement, in your
21 opinion, unreliable?

22 A. Well, that statement is based on a study that was
23 published by a Dr. Clemens in 2013, and it was a survey of
24 sling use in members of this society. But, as I tried to say,
25 what they did is they excluded anyone's survey that said they

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1 didn't use slings. And then they concluded that 99 percent of
2 AUGS members use slings, where they should have concluded that
3 99 percent of AUGS members who use slings use slings. Because
4 they did not count the ones that told them, I don't use
5 slings, and they didn't ask, why don't you use slings? Well,
6 I stopped using them because I found that there were problems
7 with safety associated with the slings.

8 The second part of their conclusion is only 55 percent
9 of people actually sent the survey back. And in their
10 conclusions they say, these opinions might not represent the
11 opinions of AUGS members at large. So they -- they qualified
12 that this was a study with a low response rate, and they
13 described in their methods that they didn't ask people why
14 they didn't use slings, and they didn't count them if they
15 said they didn't use a sling.

16 Q. Some of the things that you mentioned, you were asked if
17 you knew the differences between the slings that you used and
18 the Boston Scientific slings. You mentioned they've got
19 different pores. Do you remember that?

20 A. That is correct.

21 Q. Different polypropylenes that they're made of, correct?

22 A. That is correct.

23 Q. Different additives, right?

24 A. That is correct.

25 Q. The edges are different, right?

—Rosenzweig - Redirect - Monsour—

1 A. That is correct.

2 Q. So when companies come to somebody like you and they
3 market their products, do they come in and do they say, "Hey,
4 you ought to use my product, it's just like theirs, except
5 I've only studied it in 36 rabbits?" Do they say that?

6 A. No.

7 MR. ADAMS: Objection, Your Honor. This is leading
8 and, again, counsel's testifying, not the expert.

9 THE COURT: The objection is overruled, Mr. Adams.

10 BY MR. MONSOUR:

11 Q. You can answer the question.

12 A. The answer is "no."

13 Q. Do they tell you that their products are different or
14 maybe better than their competitors?

15 A. Yes.

16 Q. So if a company were to come into this courtroom and say
17 we're just the same as everybody else's, is that what they're
18 telling you doctors on the street?

19 MR. ADAMS: Objection, argumentative. Also, that's
20 not a proper question for an expert. It has nothing to do
21 with the case.

22 THE COURT: Do you want to respond to it, counsel,
23 before I rule?

24 MR. MONSOUR: He opened the door by asking him to
25 compare the slings, Your Honor.

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1 THE COURT: All right. I don't think that answers
2 that it is improper in its form. I'm going to sustain the
3 objection. If you want to rephrase to get into that area, go
4 ahead.

5 MR. MONSOUR: Okay.

6 BY MR. MONSOUR:

7 Q. When they come to sell their products, do they stress
8 that their products are unique?

9 A. Yes.

10 Q. Is there ever a time when you were approached by sales
11 reps from any of these companies where they tell you, "We just
12 want you to know our product is exactly like theirs"?

13 A. No.

14 Q. Now, one of the questions, one of the things that was
15 brought up is how many of the treating physicians think
16 they've got a good success rate with their products. Do you
17 remember those questions that you got?

18 A. Yes.

19 Q. And you were, in fact, asked questions about doctors
20 whose depositions you didn't even review. Do you remember
21 that?

22 A. Yes.

23 Q. Okay. And we'll assume that Mr. Adams' numbers were
24 accurate.

25 But is there any published literature out there that

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1 addresses the concept that physicians think that -- that their
2 interpretations of their own results might be misleading? Are
3 there any articles that are published on that subject?

4 A. Yes.

5 Q. Give me the name of this other article.

6 A. Well, there was a study that came out this year by a
7 Dr. Abbott who -- and her colleagues -- were looking at
8 significant complications that got referred to their
9 institution to manage. And they found that the average
10 patient had two interventions and over 70 percent -- or close
11 to 70 percent needed more than one surgery to fix their
12 complications. What they found is only 26 percent of patients
13 that came to these tertiary centers to get their sling and
14 mesh complications fixed were actually seen at another
15 institution, meaning that there is a very small chance that
16 the doctor that actually put the mesh in knew that this
17 patient even had a complication. And that was one of their
18 conclusions of this study, is that doctors probably don't know
19 that they're getting these complications, and, therefore, they
20 don't know what the level of complication is, and they will be
21 going around thinking that they're doing surgeries that have
22 very few complications because their patients are going to
23 other doctors to take care of those complications.

24 Q. So let's look at Jeanie Blankenship. Jeanie Blankenship
25 had this product implanted by Dr. Lassere. Her current

—Rosenzweig - Redirect - Monsour—

1 physician is Dr. Capelle. Is that correct?

2 A. That is correct.

3 Q. Does that happen frequently in this arena?

4 A. That is correct.

5 Q. So, if that's the case, when these physicians tell you,
6 "Oh, I've only seen one complaint," does that mean that
7 they're always following up with all of their patients?

8 A. No. And that's what the Abbott study showed, is that
9 they are not going back to the doctors who implanted the
10 slings in their bodies for their complications.

11 Q. All right. And I want to address two more things and
12 then I'm going to sit down because I'm sure you all are sick
13 of me. I know the judge is.

14 (Laughter.)

15 BY MR. MONSOUR:

16 Q. I think Mr. Adams thinks I have bushwhacked him with the
17 Cholhan and Ross studies and so I want to pull them back up if
18 we can first. I want to pull up the Ross study first. And --

19 MR. ADAMS: And, Your Honor, just an objection to
20 whatever I think.

21 THE COURT: I'm sorry. That objection is sustained,
22 Mr. Monsour.

23 MR. MONSOUR: And if we could pull up the Ross study
24 and go to the -- go to the first page of it.

25 (The document was published to the jury.)

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1 BY MR. MONSOUR:

2 Q. And let's look at this study. It's a randomized
3 controlled trial, right?

4 A. That is correct.

5 Q. It -- if you look down below, it talks about who
6 supported the study, correct?

7 A. That is correct.

8 Q. And I don't want to -- I don't want anyone to think I'm
9 sneaking up on them. If I look down below, it's a study that
10 received funding from Boston Scientific, right?

11 MR. ADAMS: Objection, Your Honor. This is
12 cumulative. I mean --

13 MR. MONSOUR: I'm just trying to clarify a point that
14 he brought up on --

15 THE COURT: I want to hear the question, Mr. Adams.
16 If there is still an objection, you let me know.

17 MR. ADAMS: I would.

18 BY MR. MONSOUR:

19 Q. This is a Boston Scientific -- funding was received from
20 Boston Scientific, correct?

21 A. That is correct.

22 Q. And if we look, it was published in what journal?

23 A. *Obstetrics and Gynecology*, that we have been calling "The
24 Gray Journal."

25 Q. "The Gray Journal." And it's not published in an obscure

—Rosenzweig - Redirect - Monsour—

1 publication, is it?

2 A. That is correct.

3 Q. And when we look at this Boston-Scientific-funded study
4 that was published in a reputable and non-obscure journal,
5 that is Level 1 evidence, when we look at the conclusion --
6 when we look at the conclusion, the last two sentences of the
7 paper, if we could pull those up, or the last three sentences.
8 I'm sorry.

9 MR. MONSOUR: That's the wrong one. Ross, last page.

10 BY MR. MONSOUR:

11 Q. It says, compared with the TVT group, the transobturator
12 group -- not this group, but the transobturator group -- had
13 tape that was palpable and groin pain. The presence of
14 palpable tape is concerning. Longer follow-up is needed to
15 determine --

16 MR. ADAMS: (Stands.)

17 THE COURT: Your objection?

18 MR. ADAMS: It's cumulative.

19 THE COURT: That objection is sustained.

20 MR. MONSOUR: Okay. Let me rephrase my question.

21 BY MR. MONSOUR:

22 Q. Did this Boston-Scientific-funded study published in a
23 reputable journal, Level 1 evidence, randomized controlled
24 trial, say don't use the Obtryx?

25 A. It said that --

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1 MR. ADAMS: This is, again, is cumulative as to what
2 he's covered on direct already.

3 THE COURT: Do you have a response? Because I tend
4 to agree. My recollection is that it was covered.

5 MR. MONSOUR: Okay.

6 THE COURT: No response? I sustain the objection.

7 MR. MONSOUR: Okay.

8 BY MR. MONSOUR:

9 Q. Let me ask this, if we can pull up one last study. And
10 pull up the Cholhan study, if you would.

11 (The document was published to the jury.)

12 BY MR. MONSOUR:

13 Q. And if you can look down in the bottom.

14 The Cholhan study, just to orient, the Cholhan study,
15 if you pull up the conclusion, is the Obtryx study that talks
16 about palpable tape and how physicians should be aware of
17 periurethral banding, correct?

18 A. That is correct.

19 Q. If we go down to the bottom of that page on the left-hand
20 corner, if we look at it, and you pull up about Dr. Cholhan,
21 it does note that he is a consultant and instructor for Boston
22 Scientific; true?

23 MR. ADAMS: Objection, Your Honor. Again, this is
24 cumulative. This was covered on direct examination.

25 THE COURT: Response, Mr. Monsour?

—Rosenzweig - Redirect - Monsour—

1 MR. MONSOUR: My response is I pulled this up for the
2 jury in my direct and I noted that he was a consultant. And
3 he made the argument that I tried to say that they paid for
4 it, and I'm trying to set the record straight because he
5 misrepresented my question.

6 THE COURT: Go ahead, please. I'm going to overrule
7 the objection.

8 BY MR. MONSOUR:

9 Q. Okay. So all I'm trying to do is establish that I'm
10 proving to the jury what I say is borne out in the documents.
11 Dr. Cholhan is a paid consultant and instructor for Boston
12 Scientific; is that right?

13 A. That is correct.

14 Q. And this was not a favorable study?

15 A. That is correct.

16 Q. Now, let's talk about the Cholhan study a little bit
17 more. You were asked about the 24 percent dyspareunia rate.
18 Do you remember that?

19 A. Yes, sir.

20 Q. In your clinical experience, can you think of a time when
21 you would talk to your patients for treatment of stress
22 urinary incontinence, when you would meet with a woman and
23 say, "Listen, I can do this procedure for you but you've got a
24 one-in-four chance of developing long-term pain with
25 intercourse"? Can you think of any woman that would say yes

1 to that procedure?

2 A. No.

3 MR. MONSOUR: I'll pass the witness.

4 THE COURT: You can step down, Doctor. Thank you.

5 (The witness left the stand.)

6 THE COURT: Call your next witness.

7 MR. LOVE: Your Honor, at this time the plaintiffs
8 would call Alex Robbins, the training manager and territory
9 manager for Boston Scientific. The plaintiffs' proffer is 17
10 minutes and 31 seconds.

11 MR. STRONGMAN: Your Honor, may we approach just
12 briefly on that?

13 THE COURT: Yes, sir.

14 MR. STRONGMAN: Your Honor, we've made some
15 objections to the exhibits that are discussed in the Robbins
16 deposition, some of the e-mails that they asked Mr. Robbins
17 about. In addition, a significant portion of the deposition
18 that's going to be played is a discussion of the Cholhan
19 study. I cannot imagine that the jury wants to listen to
20 somebody else walk through the Cholhan study again today at
21 this point.

22 MR. LOVE: This is a 17 -- this is a 17-minute, does
23 include a brief description of Cholhan, does cover different
24 parts of the study that haven't been covered yet. If you read
25 the e-mail of Dr. Cholhan, who is a paid consultant for Boston

1 Scientific, sent this study to a Kathleen Fantoni, who is the
2 worldwide global training manager for the company. She did
3 say, she sends it to this gentleman, Alex Robbins, who trains
4 key opinion leaders for the company and trains salespeople
5 nationally. And she says, I want your advice on how to use
6 this study. He says three things. He says this study will
7 not help us sell slings, it will not help us defend the
8 company -- he says four things -- it is a negative study, and
9 I would never give it to physicians, and he didn't. It goes
10 straight to claims, our negligence claim, our punitive damage
11 claim, and it refutes essentially much of the
12 cross-examination Rob Adams just did on this expert, that the
13 Cholhan study was A-OK and showed a 79 percent success rate.

14 THE COURT: You are objecting to the e-mail as an
15 exhibit, counsel?

16 MR. STRONGMAN: Yeah, well, obviously, the questions
17 regarding the e-mails as well. And Alex Robbins was a sales
18 rep. He didn't train. He was a sales rep. Didn't e-mail
19 anybody in West Virginia, certainly not the doctors in this
20 case. It's -- it's prejudicial, and, again, discussion of the
21 Cholhan study is cumulative, along with everything else.

22 THE COURT: All right. I certainly do not want to
23 permit cumulative evidence; however, if it addresses different
24 portions of that study, I think it's permissible. And, based
25 on what you all have told me about the e-mail, I find that

—Alex Robbins - By Video—

1 e-mail to be relevant with respect to the issues of the
2 plaintiffs' negligence claim and relevant with respect to the
3 punitive damages claims. So I will overrule your objection,
4 Mr. Strongman. And I preserve the defendant's objection and
5 exception to my ruling.

6 MR. STRONGMAN: Our proffer on the witness is about
7 15 minutes long.

8 THE COURT: We will get both of them in today.

9 (Sidebar concluded.)

10 (The video testimony of ALEX ROBBINS was played from
11 4:45 p.m. until 5:03)

12 THE COURT: Mr. Strongman?

13 MR. STRONGMAN: Boston Scientific has about a
14 14-minute proffer for Mr. Robbins.

15 THE COURT: Mr. Monsour, was there something further?

16 MR. MONSOUR: No. I was going to offer that was the
17 end of our proffer.

18 THE COURT: Mr. Love, when you and Mr. Strongman were
19 here at the bench, you did not refer to the exhibit number of
20 that e-mail that I admitted into evidence. Would you place
21 its number on the record for me, please.

22 MR. LOVE: I will, Your Honor. The e-mail is Exhibit
23 Number 739, and we would move for its admission into evidence.

24 THE COURT: It is admitted, preserving an objection
25 and exception for the defendant, consistent with the

—Alex Robbins - By Video—

1 conversation we had here at the bench.

2 (PLAINTIFFS' EXHIBIT 739 WAS RECEIVED IN EVIDENCE.)

3 (The video testimony of ALEX ROBBINS continued at
4 5:04 p.m.)

5 MR. STRONGMAN: That concludes our proffer of
6 Mr. Robbins.

7 THE COURT: All right. Thank you.

8 Ladies and gentlemen, I'm going to release you for
9 the evening. While you're out, do not discuss the case among
10 yourselves or permit anyone to discuss it with you or in your
11 presence, and remember that you are under continuing order not
12 to read, listen to, or view any media coverage that there
13 might be of the trial. Have a good, restful evening, and we
14 will begin tomorrow morning at 9. We'll stand in recess for
15 your purposes.

16 (The Jury left the courtroom at 5:17 p.m.)

17 THE COURT: Are there other matters, counsel, that we
18 need to address here this afternoon?

19 MR. LOVE: I've got some exhibits from depositions we
20 played the first day. I can do it first thing tomorrow, I can
21 do it now.

22 THE COURT: Let's do it.

23 MS. WEILER: We also have the medical records of
24 Ms. Wilson available. We can do those now, Your Honor, as
25 well.

—Colloquy—

1 THE COURT: Thank you, Ms. Weiler.

2 MR. LOVE: The first thing is the key points memo, I
3 don't think it's been officially offered, but it's Exhibit
4 759. The plaintiffs would offer it pursuant to the objections
5 made by the defendants.

6 MR. STRONGMAN: I think it's in evidence.

7 THE COURT: You believe that it has previously been
8 admitted, Mr. Strongman?

9 MR. STRONGMAN: I do. Mr. Monsour admitted the first
10 page --

11 THE COURT: The clerk indicates that it has been
12 admitted.

13 MR. STRONGMAN: Okay. Thank you, Your Honor.

14 MR. MONSOUR: I don't believe I -- I think I forgot
15 to offer it in its entirety. I think the first page is in but
16 I think we might need the other pages with it, Your Honor,
17 just for clarification.

18 MR. LOVE: I will make sure the clerk has a copy.

19 THE COURT: Thank you.

20 MR. LOVE: The next is from the deposition of Rob
21 Miragliuolo, and these are Exhibits 639, 525, and that's it
22 for Rob Miragliuolo.

23 THE COURT: Any objection?

24 MR. STRONGMAN: No objection on those documents.

25 THE COURT: All right. Plaintiffs' Exhibits 639 and

—Colloquy—

1 525 will be admitted into evidence without objection.

2 (PLAINTIFFS' EXHIBITS 639 and 525 WERE RECEIVED IN EVIDENCE.)

3 MR. STRONGMAN: And, actually, just say subject to
4 the issues we have already raised and that have been disposed
5 of in motions in limine.

6 THE COURT: All right.

7 MR. LOVE: Next is from the deposition of Charles
8 Smith and it's Exhibit 863, Exhibit 864 -- I'm sorry. Let me
9 back up. I was reading the wrong exhibit number. Let me
10 start over.

11 This is the Charles Smith deposition. It is
12 Plaintiffs' Exhibit 1115, Plaintiffs' Exhibit 1061, and
13 Plaintiffs' Exhibit 966.

14 THE COURT: Mr. Strongman?

15 MR. STRONGMAN: Same with respect to those, just with
16 respect -- no objection other than those that have been
17 already been raised, the motions in limine and that have been
18 denied by the Court.

19 THE COURT: All right. Plaintiffs' Exhibits 1115,
20 1061, and 966 will be admitted into evidence subject to the
21 prior rulings of the Court.

22 (PLAINTIFFS' EXHIBITS 1115, 1061, and 966 WERE RECEIVED IN
23 EVIDENCE.)

24 MR. LOVE: The final deposition is Evan Brasington,
25 and it is Plaintiffs' Exhibit 553, Plaintiffs' Exhibit 981,

—Colloquy—

1 Plaintiffs' Exhibit 517, Plaintiffs' Exhibit 564, and
2 Plaintiffs' Exhibit 532.

3 MR. STRONGMAN: Again, this is just subject to the
4 ProteGen objections that were argued on this deposition.

5 THE COURT: All right. Plaintiffs' Exhibits 517,
6 532, 553, 564, and 981 will be admitted into evidence,
7 preserving to the defendant the objections that have
8 previously been made.

9 (PLAINTIFFS' EXHIBITS 517, 532, 553, 564, and 981 WERE
10 RECEIVED IN EVIDENCE.)

11 MR. STRONGMAN: Thank you, Your Honor.

12 THE COURT: Ms. Weiler?

13 MS. WEILER: Thank you.

14 We would like to move into evidence joint medical
15 exhibits of Ms. Wilson. First is Exhibit Number 91, medical
16 records from Subhash Bhanot, M.D.; Number 92, medical records
17 regarding Ms. Wilson from CAMC Health Systems, Incorporated;
18 Exhibit Number 93, medical records of Ms. Wilson from Dr. Lana
19 D. Christiana; medical records of Ms. Wilson as Exhibit 94
20 from CVS Corporation; Exhibit Number 95, the medical records
21 of Ms. Wilson from Dr. Thopsie V. Jagannath. I will provide
22 the Court with some spellings in a moment. Exhibit Number 96,
23 medical records from Ms. Wilson from Logan Regional Medical
24 Center; Exhibit Number 97, medical records of Ms. Wilson from
25 Dr. Cyrus Mali; Exhibit Number 98, the medical records of

—Colloquy—

1 Ms. Wilson from Montgomery General Hospital; Exhibit Number
2 99, medical records of Ms. Wilson from Prestera Center;
3 Exhibit Number 100, medical records of Ms. Wilson from Rite
4 Aid Corporation; Exhibit Number 101, medical records of
5 Ms. Wilson from Saint Francis Hospital; Exhibit Number 102,
6 medical records of Ms. Wilson from Ujjal S. Sandhu, M.D.; and
7 Exhibit Number 103, the medical records of Ms. Wilson from WVU
8 Healthcare.

9 THE COURT: Anything that the plaintiff wants to
10 place on the record regarding these joint exhibits?

11 MR. LOVE: We have no objection, Your Honor.

12 THE COURT: Joint Exhibits 91 through and including
13 103 with respect to Plaintiff Wilson will be admitted into
14 evidence.

15 MS. WEILER: Thank you, Your Honor.

16 (JOINT EXHIBITS 91 THROUGH 103 WERE RECEIVED IN EVIDENCE.)

17 THE COURT: Any other matters this evening?

18 MR. LOVE: Not on our end, Your Honor.

19 MR. ADAMS: Nor ours.

20 THE COURT: Have a good evening.

21 MR. ADAMS: Thank you, Your Honor.

22 COURT SERVICES OFFICER: All rise.

23 (The proceedings concluded at 5:24 p.m.)

24 - - - - -

25

REPORTERS' CERTIFICATE

Carol Farrell, CRR, RMR, CCP, RPR, RSA, Official Court Reporter of the United States District Court for the Southern District of West Virginia, and **Lisa A. Cook, RPR, RMR, CRR, FCRR**, do hereby certify that the foregoing is a true and accurate transcript, to the best of our ability, of the proceedings as taken stenographically by and before us at the time, place, and on the date hereinbefore set forth.

/S/ Carol Farrell, CRR, RMR, CCP, RPR

11/04/14

Court Reporter

Date

/S/ Lisa A. Cook, RPR, RMR, CRR, FCRR

11/04/14

Court Reporter

Date

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